UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

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SEKISUI AMERICA CORPORATION et al,

Plaintiffs,

v. 12 CV 3479 (SAS)

RICHARD HART, et al,

Defendants.

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New York, N.Y.
January 15, 2014
10:10 a.m.

Before:

HON. SHIRA A. SCHEINDLIN,

District Judge

APPEARANCES

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(Trial resumed)

(In open court)

THE COURT: Good morning. Please be seated. Is the witness here?

MS. HAGBERG: Yes, your Honor.

THE COURT: Have him come up. Mr. Velie.

MR. VELIE: Good morning, your Honor.

THE COURT: Mr. Fryer?

THE WITNESS: Yes. Good morning.

THE COURT: Good morning.

HUGH FRYER,

called as a witness by the Plaintiff,

having been previously duly sworn, testified as follows:

CROSS-EXAMINATION

BY MR. VELIE:

Q. Mr. Fryer, you're still under oath.

A. Yes.

Q. Good morning.

A. Good morning.

Q. We spoke a little bit about your views as to Kevin Morrissey yesterday. Do you recall that?

A. I do.

Q. In fact, you came to the conclusion that Kevin Morrissey was totally incompetent, didn't you?

MS. HAGBERG: Objection, your Honor. Misstates the

witnesses's testimony.

THE COURT: It's a question.

Q. I'm not stating his testimony. I'm asking him.

THE COURT: Right.

Q. Did you come to that conclusion, sir?

A. I did.

Q. I'm going to show you, sir -- let me just ask you, you weren't the only one who shared that view, is that correct?

A. That's correct.

Q. Mr. Azary shared that view?

A. I believe he did, yes.

Q. What was his title?

A. He was the director of regulatory affairs and quality assurance.

Q. Did you also share that opinion with, here I'm, forgive me if I forget, was it Mr. Tomenori?

A. I did.

Q. He also shared your view that Mr. Morrissey was incompetent?

A. He believed there was some incompetence.

Q. Did there come a time when you believed that Mr. Morrissey was actually reading your e-mails?

A. I did.

Q. Surreptitiously?

A. I did.

Q. I'm going to show you what we've marked as Defendant's Exhibit six A's. Do you recognize this e-mail, Mr. Fryer?

A. I do.

Q. You wrote it?

A. I did.

Q. And while it's addressed to you, it says here, "Again for you illicit one." That's for Mr. Morrissey who you expected to be reading this e-mail, is that correct?

A. I did.

Q. I'm going to read this to you and ask you did this reflect your then view of the matter. "Again, for you, illicit one. Don't you think that before you claim to be an expert in something you should have some expertise in what you claim? To wit, I'm an expert in lyophilization." Then you have a bullet point. "Screwed up several of our products for many months, causing a large number of necessary back orders. Had to change the lyo back to the original cycles to correct the problems that could have been avoided had you not claimed expertise. By the way, you don't need to validate valid lyo processes. By definition they're validated."

Is that what you wrote?

A. I did.

Q. You believed that to be an accurate sum of the situation at the time you wrote it?

A. I did.

Q. Then your next bullet point is, "Screwed up a run of chromogenic material and PAI-1 Femtelle standards because you reprogrammed the lyo in the middle of a run after you warned that this would happen but did it anyway." I'm sorry. "After you were warned that this would happen, but you did it anyway. You clearly need to read directions in the future or to actually have expertise."

And that was your view of the matter at the time you wrote this?

A. It was.

Q. The next point is, "I'm an expert in plasma." And your bullet point. "Thawing plasma on a bench top, not smart."

I'm not going to read the rest of this, but that basically was your view of another screwup, if you will, by Mr. Morrissey?

A. Yes, that's true.

Q. The next point. "I know 510(k)s. I've even written one or more, I forget." A bullet point. "Claimed you wrote the manufacturing section of a 510(k). Problem is that there is no manufacturing section in a 510(k). Only in PMA's. Oops. Said this to many people so you can't deny it."

That also reflects your views of Mr. Morrissey's competence, does it not?

A. It does.

Q. Next bullet. "You also told Mike S" -- who is Mike S?

A. That would be Mike Smirnov.
Q. He was the fellow in charge of the 510(k) development for Femtelle?
A. No, he wasn't.
Q. What was he doing?
A. He reported to me and was helping with a number of projects including Femtelle.
Q. "You also told Mike S. and I that you actually wrote a 510(k) which we both highly doubt. In fact Joe" -- is that Azary?
A. That's Joe Azary.
Q. And Yoichi, is that Mr. Tamenori?
A. It is.
Q. "Also doubt that. Bring us a 510(k) with your name on it and we can confirm that you were involved by contacting the company you were working for when you wrote it."
Again, this was your view at the time of Mr. Morrissey's comments?
A. It was.
Q. Next point. "I know the IVDD." Bullet point. "Didn't know that there are no required clinical studies for diagnostic devices. In fact, after being told on many occasions that little factoid still hasn't gotten through the Neanderthal brow ridge." That was your view of Mr. Morrissey at the time, is that right?

A. That was.

Q. Next paragraph. "You've commented to Joe about"-- that's Azary again, is that correct?

A. Yes, it is.

Q. "About the mistakes I made with the 822 calculations and asked, 'Isn't this the definition of a lie?' Actually, claiming to be an expert in things you know only marginally is actually the definition of a liar and, sir, take off your hat and let me knight you with that title."

Is that your view of Mr. Morrissey's not only competence but credibility at the time?

A. Not necessarily credibility.

Q. Okay. And then you say -- but his competence, yes?

A. Correct.

Q. "You have caused us an undue amount of problems with your overblown claims. I think FDA would not be pleased with making up expertise then blaming other problems because your lack of knowledge." Again, your view of Mr. Morrissey's activities and competency?

A. Yes.

Q. In your next paragraph -- can you read it to yourself? Here I can either read it into the record or ask you about it. You're pointing out to Mr. Morrissey, who you expect to be reading this, you're challenging him to bring some batch record to management, to Mr. Takemura, is that correct?

A. That's correct.
Q. And was that because you believed the batch record to have been okay and you thought Mr. Morrissey thought it wasn't okay?
A. That's correct.
Q. You conclude, quote, "You are an unbelievably ignorant human. I'd like to see egg dripping off your face yet again. It's happened many times before." You wrote that for Mr. Morrissey?
A. I did.
Q. And then you conclude, "And by the way the entire senior management team in our Japanese owners know all of these foibles. Do you really think we're that stupid. RIP, brother." You wrote that, too?
A. I did.
Q. In fact, Mr. Morrissey testified yesterday that he'd been fired. Was he fired for incompetence?
A. I cannot answer that. I wasn't in the decision making process.
Q. Did you contribute information to the decision making process?
A. I did.
Q. And did you contribute the information of the type that's in this e-mail that I just read to you?
A. I have. I did.
MR. VELIE: Your Honor this is six B's.

Q. Mr. Fryer, is Exhibit six B's another one of the e-mails you wrote to yourself expecting Mr. Morrissey to read it?

A. I did.

Q. "Oh, illicit one. We all realize that the reason you focus your energies on compliance or what you believe we have a lack thereof is that you have little knowledge of anything else."

Does this reflect your belief at the time as you wrote it down, sir, that Mr. Morrissey believed that the company had a lack of compliance but that you believed him wrong?

A. No. I believed that he understood compliance.

Q. Let's look down in the middle of the paragraph. The sentence that begins, "What you pass off as knowledge is actually opinion, nothing more." I'll read the rest of this. "All of the senior managers get this. Many employees with a brain in their head and who think for themselves also are on to your little dance. You really aren't fooling any of us. Joe" -- that's Azary, correct?

A. It is.

Q. "Is sick of your strange interpretations of FDA regs. But continue on this path. You make the rest of us look like geniuses." That's what you wrote for Mr. Morrissey?

A. I did.

Q. That was your thinking at the time?

A. It was.

Q. Next paragraph. "By the way, lest you think you can use

these e-mails against me, I've already had a discussion with Takemura-san about you spying on my e-mail." That's the Mr. Takemura who testified here on Monday, is that correct?

A. Yes, it is.

Q. He's the executive in charge of ADI at the time, right?

A. He was.

Q. "I told him that you would make up some tale as to why you were doing so, other than trying to justify making me look bad. He gets it. Bring any of this to his attention and he won't be getting anything he hasn't already heard from most of the senior managers. In fact, he and I have had this same discussion that I outlined above." Is that correct?

A. That's correct.

Q. And in fact what you outlined above is the stuff I read you just a moment ago from this very e-mail. When you say "above" you mean the first paragraph?

A. I believe so, yes.

MR. VELIE: Six C's, your Honor.

Q. Take a moment to read this, please, Mr. Fryer, because it's an e-mail chain which includes an e-mail chain, so reading it is a little bit complicated. Tell me if I'm correct about this after you've had a look at it. Have you now had a chance to look at it?

A. I'm still reading. I'm sorry.

Yes.

Q. Okay. Tell me if this is the order in which this goes. The first one is Joe Azary to you in June of 2012 where he says "The term megalomaniac comes to mind as well," correct?

A. Correct.

Q. And that encloses an e-mail -- actually, it responds -- no, it encloses an e-mail which encloses a chain, is that correct?

A. That's correct.

Q. Okay. Now, I've tried to figure this out and I think the chain goes this way. The bottom of the page, Azary to you on June 8 is the first, right?

A. I believe it is, yes.

Q. Okay. And basically this is something he sent to you and then you responded, is that right?

A. I believe yes.

Q. Okay, and your response is immediately above it on Sunday, June 10, from you to Joe Azary. Quote, "We had a long teleconference with Paul O'Connor and Carol on Friday. They felt that because our quality system was such a mess they fired Mir Kahn. You will be sent a letter terminating you as of Wednesday of last week. They also decided to hire a QA consulting company. Since we only wanted the best, we hired a company by the name of AQSOL. A Kevin Morrissey will be here on Monday." Mr. Morrissey then worked for AQSOL, is that correct?

A. I believe he was working for him at the time.

THE COURT: I'm sorry?

THE WITNESS: I believe he was working for him at the time.

THE COURT: For him, you mean for AQSOL?

THE WITNESS: Yes.

Q. Then you go on. "I'm looking forward to working with him. I've heard good things about his experience with vast IVD's (information verified to be dumb). He also has a large number, more than 1800 510(k)s that were submitted to the Costa Rica FDA."

Now, sir, this is an attempt at humor, isn't it?

A. It was.

Q. Basically the irony in this is this reflects you believe he had no vast experience in quality in IVDs nor in 510(k)s, isn't that correct? That's the irony of your statement.

A. Yes.

Q. You continue. "Now I wake myself from that nightmare and thanks to the big one that's over. I'm sure you feel the same that you don't need to make the two-hour schlep back and forth to Stamford. Just wanted to wish you luck and fun tomorrow."

And so this reflects you and Mr. Azary's views of Mr. Morrissey, is that correct?

A. That's correct.

Q. And then the top of the chain is -- this is you to Azary. Was going through some old papers and found the one attached.

Based upon some conversations we had in the past I thought you might find this interesting. And underneath is Azary to you or -- Azary to you, yes. "Enjoy the experience. I was once told by someone with 450,000 years experience in IVD" -- that's Mr. Morrissey, right?

A. Correct.

Q. "I was once told by someone with 450,000 years experience in IVD that quality can only be achieved by shutting down production, not shipping product, spending hundreds of thousands of dollars and creating piles of paper. It is only until that point can true quality be experienced."

And then you write "LOL". That means lots of laughs doesn't it, or does it mean laugh out loud?

A. I'm sorry. I didn't write that. That was from Joe Azary.

Q. What do you understand LOL to mean?

A. Laugh out loud.

Q. So again Mr. Azary is pointing out his views of the efforts of Mr. Morrissey when he was president of the company when he, Morrissey, was president of the company, is that correct?

A. That's correct.

Q. You shared that view?

A. I did.

MR. VELIE: Defendant's Exhibit five I's, please.

Q. This is in evidence, Mr. Fryer. Why don't you read it? It's an e-mail chain. Start at the bottom and go to the top.

A. Okay. This is an e-mail from Mamoru Koseki to Dicey Taylor.

Q. And that says -- it's short, I'll read it if I may, your Honor. "I need to find out," this is, the date on this for everybody is June 11, 2010. Mr. Koseki at that time reported to Mr. Morrissey, if you know?

A. No. Well, let me -- let me check the date.

Q. June 2010.

A. No, he did not.

Q. "Dicey-san, I need to find out whether Richard's old e-mail" -- that's Richard Hart, right?

A. It is.

Q. "Old e-mail shows evidence that he knew what was going on in manufacturing, especially communications among Richard, Vince, David and Robert are of interest. How far back can you trace their e-mail records? Let's discuss this next week. Best regards, Mark."

And then the next one names you, so I'm going to read it to you. It's from Dicey to Mr. Koseki, June 11, same day. "Dear Koseki-san, we can go back to 2003 when the company was established here in Stamford, but Hugh," that's you, right?

A. That is me.

Q. "Has already addressed the matter. He says he has files of e-mails from Bhavna and Enri, who is Enri?

A. Enri Guinto who reported to me.

Q. Who is Bob?
A. Bob Equad was also somebody within the R and D group.
Q. "So he," he, meaning Hugh Fryer, "says he has files of e-mails from Bobna and Enri starting in 2004 when they complain in e-mails to Richard that we were making products with expired materials and they wanted his help to correct these problems. Hugh" -- that's you, right?
A. It is.
Q. "Will give me these e-mails on Monday. He says most of the e-mails concern all the products that we had to put recently into quarantine." Now, sir, did you in fact collect a file of those e-mails?
A. I had a few e-mails, yes.
Q. And did you turn them over to Dicey Taylor?
A. I believe I did, yes.
Q. Have you seen them since?
A. No, I have not.
Q. Were they given to you in your preparation for this testimony?
A. No, they weren't.
MR. VELIE: Your Honor, this next should be very quick. 22 and Defendant's Exhibit five H's.
MS. BRILEY: PTX 22 is already in evidence.
THE COURT: So I can pull it up and so can you.
MR. VELIE: Sure.

MS. BRILEY: I'm going to give them a copy of this and then we're handing out our exhibit.

THE COURT: Why are you giving them a copy?

MS. BRILEY: Just so they know what we're turning to. And this is a new one, this is a different exhibit. We're using them both.

THE COURT: Not 22?

MR. VELIE: Here comes five H's.

MS. BRILEY: It relates to 22.

THE COURT: I pulled up 22 and now five H will relate to.

Q. Do you have 22 in front of you, Mr. Fryer?

A. I don't believe -- oh, I'm sorry, yes, I do.

Q. Plaintiffs 22 is, is it not, the Femtelle 510(k) which was submitted prior to the 2009 Femtelle 510(k) which we've been mostly talking about?

THE COURT: I'm sorry, your question totally lost me. 22 which I have on the screen is dated January 31, 2000, right? Is that right? It's a letter to Mr. Jonathan Kahan at Hogan & Hartson? That's Exhibit 22. To Richard Hart --

MR. VELIE: Excuse me, your Honor, I just need our copy to see if I'm doing the right thing.

THE COURT: It's from Richard Hart. It contains two bundles of pages --

MR. VELIE: Your Honor, perhaps we don't need to

trouble the witness with this, but if you'll accept Defendant's Exhibit five H's in evidence, we are going to be able to show either through this witness or otherwise that substantially it's same document as Plaintiff's Exhibit 22 with one or two slight differences.

THE COURT: The cover page of DX five H says 2008 510(k). So that's what this purports to be, the 2010 510(k)? Did I say 2010? I meant 2008 510(k).

MR. VELIE: Yes, your Honor.

MR. VELIE: I'll ask Mr. Fryer.

Q. In fact, this is the 2007 510(k) and you so testified yesterday when you saw PX 22.

THE COURT: I'm sorry, you can't ask that. You said "this". I don't know what "this" refers to.

Q. PTX 22, when you were shown it yesterday, despite the fact it says something on it about 2008 is indeed the 2007 510(k) that everybody has been talking about as the 2007 510(k), is that correct?

A. That's correct.

THE COURT: Okay, hold on. So you're telling me Plaintiff's Exhibit 22 starting with a cover letter from Jonathan Kahan at Hogan & Hartson is the 2007 510(k)?

Q. Is that correct, sir?

THE COURT: You keep pointing to something in your hand. We're both looking --

Q. I'm only talking about Exhibit 22. Exhibit 22 is an enclosure letter and the 2007 510(k), is that right?

A. This is an enclosure letter with the 510(k).

THE COURT: The 2007 510(k).

THE WITNESS: 2007 510(k) is attached.

Q. Now, take a look at Defendant's Exhibit five H's.

A. Okay.

Q. Is this also the 2007 510(k)?

A. Looks like it is, yes.

THE COURT: Well, why does the cover sheet say Femtelle 2008 510(k)?

THE WITNESS: I've never seen this particular cover sheet.

THE COURT: Oh. Okay, so how do you know it's the 2007 510(k)? It's dated April 25, 2008, to Richard Hart from Leigh Ayres. Do you see that?

THE WITNESS: Yes, I do see that.

THE COURT: So how do you know that's the 2007 510(k)?

Q. Start with the third page --

THE COURT: Can you let him answer? Thank you.

THE WITNESS: This is essentially the information that was enclosed with the 510(k) of what we were calling the 2007. I believe actually, if I'm not wrong, I believe this was actually submitted in 2008, but we were --

THE COURT: Well, on the third page, as Mr. Velie

tried to tell you, the Bates stamp at the bottom is SEK 2014. Do you see that at the bottom?

THE WITNESS: No, your Honor, I don't.

THE COURT: About the fourth page in.

THE WITNESS: Yes.

THE COURT: Just look at the Bates numbers. 2014. Do you see that?

THE WITNESS: I do.

THE COURT: The upper left-hand corner date of submission February 7, 2007, that's how we know it's the 2007 510(k)?

THE WITNESS: Yes.

THE COURT: Good.

MR. VELIE: Thank you, your Honor. Thank you for helping me out.

THE COURT: No, you pointed out that page. We can thank each other. Okay.

MR. VELIE: The point of this, your Honor, I may not need the witness further, is that what the plaintiffs have offered is the 2007 510(k) showing Hart numbers and what this is is the 2007 510(k) showing Sekisui Bates stamp numbers and I won't make argument now, but we wanted to show that it was in their files and available to them.

THE COURT: Okay. Well, certainly the Bates stamp would reveal it came from Sekisui files. Right, Ms. Hagberg?

MS. HAGBERG: Your Honor, we're not disputing it. We can't say they're exactly the same.

THE COURT: I don't know that either, but I'm just saying this 2007 filing, February 7, 2007 as indicated on Bates 2014 certainly came from Sekisui's files.

MS. HAGBERG: I don't know as I stand here where it came from, but we did produce this document.

THE COURT: You produced it but you can't say where it came from.

MS. HAGBERG: I can't say as I'm standing here today whose files or where we got it from, but, yes, we produced it.

THE COURT: But anything --

MS. HAGBERG: It had to come from somewhere related to the litigation.

THE COURT: Not from Sekisui?

MS. HAGBERG: I don't want to say something that I don't know for certain.

THE COURT: So you don't have that stipulation yet, Mr. Velie, that they collected documents from somewhere other than Sekisui.

MS. HAGBERG: I don't want to say anything that I don't know to be accurate, your Honor.

THE COURT: I understand. Maybe you can look into it and see where this particular document, Sekisui 2010 through 2191 came from.

MS. HAGBERG: Of course, and I certainly agree we produced it.

THE COURT: She agrees she produced it. She will look into it and get back to us where the document Sekisui 2010 through 2191 came from.

MR. VELIE: Thank you, your Honor. That's the purpose of this.

THE COURT: If she can identify where it came from, that would be helpful.

MR. VELIE: May I have a moment to consult?

THE COURT: And may I ask do you need me to keep 22 open on the screen or not?

MR. VELIE: We don't need it any longer.

(Pause)

MR. VELIE: We're going to work next with Defendant's Exhibit four J's. Give me a moment, sir. May I have a moment, your Honor?

(Pause)

Q. I just want to call your attention to the little bit of testimony you gave yesterday about a representation made to KPMG from the company about 80 percent chance of success for Femtelle. Do you recall? I'm not testifying. I'm just asking do you recall whatever it is you said on the record yesterday on that topic?

MS. HAGBERG: Your Honor, misstates the witnesses's

testimony.

THE COURT: He just clarified it. He said he's not trying to summarize it, he just wants to --

Q. I just want to call your attention to that little bit of testimony. Do you remember about the 80 percent?

A. I remember the discussion.

Q. Did you participate also, and take a look at page 5 --

A. Yes.

Q. You did participate?

A. I'm sorry, no, that wasn't the answer to your question. I was just pointing out that I was looking at page 5.

Q. I need the next page as well. Oh, here it is. It says here, "Please provide the carrying amount of Femtelle as of the valuation date," and the valuation date --

A. I'm sorry, which page are you?

Q. I'm on page 5. The answer is 3.6 million given by the company, and I'm just trying to find for you the valuation date. As of October 1, 2012. It shows on Sekisui Bates stamped ending in 19. Did you participate in discussions with management at or about this time with respect to the Femtelle project?

A. I've had discussions with -- yes.

Q. And if you know did any of your communications bear on the issue of the valuation of Femtelle as represented to KPMG? If you know.

A. I don't know.

MR. VELIE: Again, your Honor, I need a moment.

Q. Let me just ask you with respect to the $3.6 million, anything in your conversations with management at that time that would contradict this valuation as of that valuation date?

MS. HAGBERG: Objection. No foundation.

THE COURT: He's asking, he's asking whether anything in your conversations with management. If he has no knowledge, he'll say no. Otherwise he'll say yes and tell us what it is.

A. I'll be honest to say that I don't know what valuation actually means.

Q. I'm just asking, as you sit here today and look at that value, is that inconsistent in any way with what you think you were telling management?

MS. HAGBERG: Objection, your Honor. He has no basis for responding to that question, he's just said.

THE COURT: I'm sorry, I'm now confused. He might be, too. First of all, let me find this -- are you looking at four J's somewhere?

MR. VELIE: Yes.

THE COURT: Which page?

MR. VELIE: Page 5 is the valuation page.

THE COURT: Page 5.

MS. HAGBERG: Your Honor, he just testified he doesn't know what a valuation is.

THE COURT: I agree. I want to look at it myself. Which part of page 5?

MR. VELIE: It's the last major grouping, KPMG followup.

THE COURT: "Please provide the carrying amount of Femtelle as of the valuation date 3.6 million"?

MR. VELIE: Yes.

THE COURT: Who prepared this document?

MR. VELIE: KPMG.

THE COURT: Right. And who provided that number?

MR. VELIE: The company. Is that correct?

THE COURT: KPMG? No, the company is answering KPMG's question.

MR. VELIE: That's my understanding.

THE COURT: What's your question to him now? Did you have any role in that number, in setting that number?

THE WITNESS: I don't believe I did

THE COURT: No. All right. All right. And you don't know how it was reached?

THE WITNESS: No, I don't.

THE COURT: Okay.

Q. Plaintiff's Exhibit 210, can you put that in front of you?

A. I have it.

Q. Were you testifying that this particular batch went into a kit that was used, sold for commercial use?

A. Yes.

Q. Okay. I need seven H's, I believe.

MS. BRILEY: Here you are. We need to mark this, it hasn't been marked yet but it will be DX seven H's.

MR. VELIE: May I suggest since we haven't put a sticker on it --

THE COURT: 7H?

MR. VELIE: 7H's.

THE COURT: That's what I'm going to do. I'm going to put DX seven H's.

MS. BRILEY: And on this we also have the metadata.

MR. VELIE: Your Honor, I'm no technician but I believe that explains why it doesn't have the Bates stamp.

THE COURT: I understand that. So this is January 24, 2007. And it's a quotation to, sold to Quest by ADI.

MR. VELIE: Your Honor, with respect to your comment sold to, I'm going to ask --

THE COURT: It's a quotation.

Q. It says for evaluation purpose and the amount due is shown as zero. In other words, this wasn't sold at all.

THE COURT: Well --

Q. Is that correct, Mr. Fryer?

THE COURT: Excuse me, he wasn't there in 2007, right?

THE WITNESS: No. I was there in 2007.

THE COURT: Oh, you were there in 2007. I stand

corrected.

Q. As you look at this document, this is the document that orders the particular thing you were talking about yesterday?

A. Yes.

Q. When you spent time talking about Plaintiff's Exhibit 210, is that right?

A. Yes.

Q. And this is Quest ordering it or American Diagnostica, ADI, responding to the purchase order by saying it's for evaluation purpose and no cost.

A. Our procedure was to send Quest two kits for their evaluation before we could release it to sale for them.

Q. And the particular batch you were --

THE COURT: Excuse me, where does it say for evaluation purposes, just so I see it?

MR. VELIE: In red, right on the front page.

THE COURT: Ah, got it, thank you. Go ahead.

Q. In fact, the particular batch you were talking about in Plaintiff's Exhibit 10 is the very batch that is described here, isn't it?

A. Yes, it is.

MR. VELIE: We're now going to look at Exhibit seven I's.

MS. BRILEY: I only have three. This will be marked Defendant's Exhibit seven I's.

MR. VELIE: I'm the one who doesn't get one. For witness and their counsel. And again, we premarked this -- have we marked it?

MS. BRILEY: It will be seven I's.

MR. VELIE: Seven I's. Please write that on.

Q. Mr. Fryer, you can see that Quest promptly wrote back and said that they had tested it and found it acceptable for its purposes, is that correct?

A. That's correct.

Q. And that's that particular batch you were talking about yesterday.

A. That's correct.

Q. When you used your pointer and pointed at the screen?

A. Yes.

Q. Okay.

MR. VELIE: Let's do DX S.

Q. Okay. There's another exhibit which we don't have a copy of which suggests that -- well, let me just ask. You were aware of the Trinity audit, weren't you?

A. Actually, I wasn't.

Q. Who is Trinity Biotech?

A. Trinity Biotechnology is another diagnostic company which was located at the time in I believe in Ireland.

Q. And you can see from this that Trinity Biotech did what I've been perhaps ignorantly referring to as a customer audit

that I think some people refer to as a supplier audit?

MS. HAGBERG: Your Honor, there's no foundation for this question.

Q. Which do you prefer?

A. Correct.

THE COURT: I --

MS. HAGBERG: It's okay.

THE COURT: It's okay?

Q. We have another exhibit which we are calling --

MS. BRILEY: DX seven J's. We'll need to display that on the computer because the printout copy is missing an attribution on the top. I can give you this or try to get another copy, whichever you prefer, your Honor.

THE COURT: You said you would put it on the screen?

MS. BRILEY: It's that document.

THE COURT: That's fine.

Q. Are you able to see that, Mr. Fryer?

A. I am.

Q. Is this an e-mail from David Teicher and it's to you, among others? Do you see your name there?

A. Yes, I do see my name.

Q. So you got this e-mail and the subject is audit by Trinity Biotech?

A. I see that, yes.

Q. "To all: A reminder that Trinity Biotech USA will be here

tomorrow to conduct an audit on" -- and I can't read what that says. "This audit is limited to our QMS and 843L, no other products. Those in manufacturing please clean/straighten up the benches as much as possible." That's David Teicher, right?

A. It is.

Q. So you were aware of this --

MS. HAGBERG: Your Honor, we didn't get a copy of this. May I have a moment?

MS. BRILEY: It came from your --

MR. WHITNEY: We just haven't identified.

Q. So you knew that Trinity was going to do an audit?

A. I received the e-mail, I don't recall.

Q. Sir, it was a relatively small place, isn't it?

A. It is.

Q. You talked to David Teicher every day?

A. Not back then I didn't.

Q. A lot?

A. Not at that time, no.

Q. Did you talk with other people about what was going on with the business?

A. I did, yes.

Q. Did anybody ever tell that you there was a disappointing result from the Trinity Biotech audit?

A. I don't recall.

Q. Well, you would have if they failed it, wouldn't you?

A. If we failed it, I would have probably known.

Q. Okay. So is it fair to say that whatever if anything you heard further about Trinity Biotech was favorable?

MS. HAGBERG: Objection, your Honor. No foundation.

THE COURT: Sustained.

Q. Let's take a look, sir -- first of all, this is an audit for -- look on page 926, Sekisui 926.

MS. BRILEY: We're going to another exhibit, DX S.

MR. VELIE: I'm sorry. If I'm not being clear, we're in DX S which I believe is in front of everybody.

THE COURT: Right.

MR. VELIE: Page 926. It's about the third page in.

(Continued next page)

BY MR. VELIE:

Q. Do you know what kind of audit it was? It's a QSR and an ISO audit, is that correct?

MS. HAGBERG: Objection, your Honor. The witness said he has no knowledge of this and doesn't know about the audit.

THE COURT: Right. Why are you asking about it if he doesn't know?

MR. VELIE: Because he testified to things that are inconsistent with this audit, your Honor. I'm going to ask him --

THE COURT: You want to impeach with this audit, then don't ask him if he does. Just show it to him and point out and say does that effect your previous testimony.

MR. VELIE: Thank you.

Q. QSR means it's of FDA standards, isn't that correct?

A. Yes.

Q. It was also ISO standards, ISO standards?

A. There are ISO standards.

Q. Yes. And when if you look at the box on 926 it tells you -- well, it doesn't tell you. I apologize. 1 and 3, yes, it does.

If you look -- yeah. 1 is Q, where it says QSR. If you look down to the next box, there is an X indicating it is a QSR audit, is that correct?

MS. HAGBERG: Objection, no foundation.

THE COURT: He knows how to read these. You've seen these, haven't you?

THE WITNESS: Not this particular one. They're all a little bit different.

THE COURT: True, but --

A. I see an X, yes.

Q. Okay. So that means it was a QSR audit?

A. Yes.

Q. Okay. And ISO is number three. You see that it was also an ISO audit, is that correct?

MS. HAGBERG: Objection to the characterization of the document. There are two ISO's there.

Q. They're both checked, aren't they?

THE COURT: 1 and 3 are both checked, column 1 and 3 are both checked, right?

THE WITNESS: Yes, they are.

THE COURT: Okay.

Q. Okay.

THE COURT: So whether it's ISO 9,000 or ISO 13485, either way, columns 1 and 3 are both checked.

THE WITNESS: They are. They're both checked.

THE COURT: Okay.

Q. I want you to look at the very first page of this exhibit, which is Bates stamped 924. It's from Leigh Ayres. It's an e-mail from Leigh Ayres to Richard Hart attaching this audit

report, is that correct?

THE COURT: You don't need him to tell you that. It's correct. I see that. That's correct.

Q. Leigh Ayres says, there were no audit observations, but there were two suggestions for improvement presented on the second to last page of the --

THE COURT: That's not a question for him. That's what the document says.

MR. VELIE: Thank you.

THE COURT: Okay.

Q. On page 929, does the document say --

THE COURT: That's not a fair question. Does the document say is silly. If you want to read from the document, in evidence, you may. What do you want to read?

MR. VELIE: On page 929?

THE COURT: Yeah.

MR. VELIE: Raw material and component control.

THE COURT: Yes, that's the title. Go ahead.

Q. Third box. "Are materials quarantined until evaluated for conformance to specifications? Yes. See SOP GEN 020, Section 6.22. Looked at areas during walk through. X, restricted access cage for preprinted labels. X. Physical segregation X labeled."

THE COURT: Yes, that's what the document says.

Q. Dropping down. "Are raw materials labeled with status and

adequately controlled? Yes. See SOP GEN 20, Section 6.2 and 6.5. Noted at walk through. Physical segregation labeled."

THE COURT: Yes, that's what document says.

Q. Dropping down.

"Is nonconforming material segregated, identified and reviewed for disposition by appropriate personnel? Yes. See SOP GEN 20, Section 6.2, 6.5 and 6.7, reviewed at audit and at walk through. Physical segregation, labeled material, disposition by responsible department."

THE COURT: Yes, the document says that.

Q. Right below it. "Does the supplier ensure that nonconforming product is accepted by concession only if regulatory requirements are met? Yes. See SOP GEN 032, Section 6.48.

Is the identity of the person authorizing the concession recorded? Yes. See SOP GEN 32. Reviewed at audit."

Next. "If materials deteriorate over time, are there procedures to assure that only acceptable materials are used in the product? Yes. The Solomon system tracks expirations dates."

What's a Solomon system, sir?

A. That was our financial accounting system.

Q. And was it being used to assure that only acceptable materials are used?

A. I can't say for any certainty. I don't know the system.
Q. You see that the auditor says so, is that correct?
A. Yes.
Q. Okay. "Are labels inspected prior to release? See SOP GEN 20, Section 6.2 and 4, SOP 30, Section 6.2, segregated during storage and use. And are they accounted for after completion of any labeling operation? Yes. See SOP GEN 30, Section 6.3, 6.5. Reviewed the audit. Only correct amount printed for forward in-house labels and labeling. Usage reconciled for preprinted labels, labeled with expiration date."

Next page. "Are finished goods handled to prevent damage and deterioration? Yes, SOP GEN 20, Section 6.1."

MS. HAGBERG: Your Honor --

MR. VELIE: "Reviewed at audit."

MS. HAGBERG: -- he's just reading this into the record.

THE COURT: I know. Yes, he is, and I don't know why, but reading it into the record. At some point I guess he's going to say, do you think this is incontinent with what you testified to. I mean, I hope we get there soon.

MR. VELIE: Yes, we'll get there soon, your Honor.

Q. "Are finished goods handled to prevent damage and deterioration? Yes. See" -- I'm sorry -- yes, "see SOP GEN 20 Section 6.1 reviewed at audit," and then "The observation are stored at recommended label temperature."

That is an observation here, is that correct?

THE COURT: No, no. I thought you couldn't ask him that. You're reading it, you want to read from a document in evidence.

Q. "Stored off the floor protected from environment segregated from any process materials, all indicated in X's in the boxes. Are there document procedures for the control of product with a limited shelf life requiring special storage conditions, and are these special storage conditions controlled and recorded? Yes. See" -- and then there's an EQP 047, for each medical device. Where applicable, does material traceability exist throughout the manufacturing process into storage and shipping? Yes. See SOP GEN 20. Reviewed at audit." And then the X's on per production records M.R. Systems Solomon, the X's are so recorded. Does the supplier establish document and maintain procedures for traceability? Yes."

Now, are you testifying, sir, that despite these specific audit findings by the Trinity auditor, that you did not have satisfactory procedures in-house?

A. I am.

Q. Okay. So you simply disagree with the audit?

A. Correct.

Q. Okay.

MR. VELIE: I have no further questions for this witness.

THE COURT: Okay.

REDIRECT EXAMINATION

BY MS. HAGBERG:

Q. Let's start with DXS, Mr. Fryer, since that's in front of you?

A. Yes.

Q. That's the one that Mr. Velie just read the entire report to you. Do you know what --

MR. VELIE: Excuse me.

THE COURT: It wasn't the entire --

MR. VELIE: Page and a half of it. There are a lot more --

THE COURT: I got that. Please don't waste time. I agree. It wasn't all of it, it was a lot of it. Go ahead.

Q. Do you know what Trinity looked at when it came to ADI in September 2008 to audit, do a supplier audit of ADI?

A. I can't say for all certainty, but it seems like their focus was, really was on the one product that we had, which was 843L.

Q. I'm asking you, do you have any knowledge of what they looked at when they came to do the audit?

A. No. No knowledge.

Q. Do you know how thorough Trinity was in conducting the audit?

A. I have no idea.

Q. Do you agree with the conclusions that Mr. Velie read out of the report?
A. No, I don't.
Q. One of the conclusion said that the Solomon system which -- and you said it has financial information. Did anyone ever tell you to look in the financial data system for information about expiration dates?
A. No.
Q. Does that one answer that Trinity put in that document make you question the rest of the findings that are set forth in DXS?
A. It does.
Q. Now I'd like you to look at what was -- and I apologize, I don't have the document exhibit number on this, but it's the February 5, 2000 e-mail from Susan Ruden to Garcia Raphael?
A. Yes.
Q. This e-mail, what's the date on this e-mail?
A. February 5th, 2007 or --
Q. And could you look back -- I apologize, your Honor -- could you look back at PTX-2, page S -- 210, SEK, page 877 which I think is the third and fourth page in this document?
MS. HAGBERG: That's PTX-210, your Honor.
A. Yes.
Q. What was the date that ADI extended the expiration to without any confirmation testing beforehand?

A. April 22nd, 2008.
Q. Now, I'd like you to look at DX seven H's, which is an ADI quotation to Ms. Susan Ruden?
A. Yes.
Q. Do you have that?
A. I do.
Q. Is Imubind Plasma PAI-1 ELISA an IVD product?
A. It is.
Q. And could you explain what you understand this document DX seven H's to be?
A. My understanding is that with Quest we always sent evaluation kits for them to test prior to the release, prior to the sales to Quest.
Q. And would those kits be in a form that they could be sold then to the market by Quest after they received the rest of their order?
A. Yes.
Q. And I believe you testified yesterday with respect to 210, that the order was for 300 kits, is that right?
A. That is correct.
Q. Now I would like you to turn to DX six A's, and that's your e-mail dated December 25?
THE COURT: Which one again?
MS. HAGBERG: Six A's, your Honor.
THE COURT: Six A's. One second. There is a lot of

paper up there. This is working in paper.

Okay. Oh, that's the Christmas one.

MS. HAGBERG: Christmas one, exactly.

THE COURT: Yes.

Q. And as Judge Scheindlin just noticed, were you writing this on Sunday, Christmas day?

A. I was.

Q. And why were you writing this?

A. I believe that my e-mails were being read by Kevin Morrissey.

Q. And why were you writing it on Christmas day to yourself?

A. I wanted to send him a message.

Q. Were you having a personal dispute with Mr. Morrissey at the time of this e-mail?

A. I was.

Q. And what was that dispute about?

A. Management style.

Q. And was there a division within the company between you and others on one side and Mr. Morrissey and others on the other side?

A. That's an accurate description.

Q. Were both sides of that dispute trying to do what was best for the company, in your opinion?

A. We all believed we did, yes.

Q. Did the fact that you were having a personal dispute with

Mr. Morrissey, influence the comments that you made in this e-mail?

A. Yes.

Q. And when you said on 880, RIP, brother, were you trying to get Mr. Morrissey fired?

A. I was.

Q. Now, let's -- and, in fact, Mr. Morrissey got fired, right?

A. Yes.

THE COURT: Well, look, but dispute or no dispute, and style or no style, you really didn't think much of him in these areas, right?

THE WITNESS: That's correct.

THE COURT: That's true.

Q. What was your FDA experience as of December 25th, 2011?

A. Not very much.

Q. And what was Mr. Morrissey's experience as of December 25th, 2011?

A. Much greater than mine.

Q. Could you now look at DX six B's?

THE COURT: Six B's?

MS. HAGBERG: Six B's as in boy, your Honor.

THE COURT: I got to find it, which will take forever.

MS. HAGBERG: That's another -- that's the post January 1, 2000.

THE COURT: Yes, okay.

Q. Do you have that document in front of you, Mr. Fryer?
A. I don't -- yes, I do.
Q. And again you're writing this e-mail to yourself, is that right?
A. That's correct.
Q. Is this in your efforts to continue to create a record to get Mr. Morrissey fired?
A. No, that wasn't the intention.
Q. What was the intention of this document?
A. It was to inflame him.
THE COURT: To what?
THE WITNESS: To inflame him.
Q. And why did you want to inflame him?
A. Because I believe he had -- he was reading my e-mails.
Q. Okay. Now, yesterday Mr. Velie asked you whether there would be a -- whether you feared or ADI feared there would be an audit if the 510(k) for Femtelle went forward, and you said yes. Do you remember that?
A. I do.
Q. Could you please turn to PTX-93? And that was your regulatory GAP analysis I believe?
A. Okay.
Q. Do you have that in front of you?
A. I do.
THE COURT: I'm sorry, which one is that?

MS. HAGBERG: PTX-93.

THE COURT: 93? What is this, what is PTX-93?

MS. HAGBERG: He testified about this yesterday.

THE COURT: I know.

Mr. Fryer, what is PTX-93?

THE WITNESS: I'm sorry. This is a regulatory GAP analysis that I was asked to write to look at some of the issues surrounding the 510(k) -- around Femtelle and the 510(k) filings.

THE COURT: What? I'm sorry, what, the last thing?

THE WITNESS: The regulatory issues that surrounded the 510(k) filings for Femtelle.

THE COURT: What year?

THE WITNESS: The 2009 -- the 2008 submission.

THE COURT: How do you know it relates to the 2008 submission?

THE WITNESS: It was based -- I'm sorry. It was based upon the information that, the most current information we had available, which was from the 2008 submission.

Q. Mr. Fryer, you said 2008 submission. Is that -- did you misspeak?

A. It really was to look at all of whatever we had for Femtelle at the time, which included information that came from the 2008 submission.

Q. And my question is what concerns, if any, did you have

about the pending 510(k), other than risk an audit?
A. Well, there was a lot of problems, especially with not having a design history file and traceability on our patient data to our, our -- the kits that were used for the testing.
Q. And did you consider -- and I think you said yesterday that there were other issues that were -- that you needed that were listed in number six on SEK-432, is that right?
A. That's correct.
Q. And did you consider the concerns that you just mentioned and the ones in number six on SEK-432 to be minor concerns?
A. On section six?
Q. Yes, in section six and what you said about missing a design history file and missing data, did you consider those to be minor concerns?
A. No. Those are major concerns.
Q. You also said yesterday that you knew that objections FDA had made regarding the 510(k) submission from 2007, is that right?
A. I did.
MS. HAGBERG: Your Honor, may I approach and hand the witness PTX-31?
THE COURT: Why are you doing that on paper? It's fine.
MS. HAGBERG: It's what I have because it's a redirect based on testimony.

THE COURT: I have that?

MS. HAGBERG: Okay.

THE COURT: I'm asking. I have it electronically?

MS. HAGBERG: PTX-31.

THE COURT: Right.

MS. HAGBERG: Just in case he wants --

MR. VELIE: Your Honor, we have two objections to this. This was not designated as an exhibit that would be used on his direct. It was not used on his direct. It was not used on my cross.

THE COURT: But it may relate to something that came out on your cross. This is redirect.

MS. HAGBERG: That's correct, your Honor.

MR. VELIE: If it relates to my cross, it will, but I don't believe that it does.

THE COURT: Okay. Well, she represents, Ms. Hagberg is representing that it does relate to your cross.

Go ahead.

Q. And what were the reasons that you are aware of that the FDA had concerns about the 2007 510(k) submission for Femtelle?

A. I'm sorry, can you repeat the question?

Q. Yes. You said you were aware of what the reasons were that the FDA had concerns about the 2007 510(k) for Femtelle, and I'm asking you what the FDA's concerns were?

MR. VELIE: Excuse me, your Honor. That's exactly the

point. The only thing I asked him about was a 2009 Femtelle.

THE COURT: No.

MR. VELIE: To which he said there were minor --

THE COURT: No, you asked about the 2008.

MR. VELIE: No.

THE COURT: I remember.

MR. VELIE: I didn't. I only had him identify the exhibits.

THE COURT: That's right.

MR. VELIE: Period.

THE COURT: Right.

MR. VELIE: This is a whole new area here on what was wrong, they say, with the 2007 Femtelle.

THE COURT: Yes. Was there any questioning about the 2007?

MS. HAGBERG: Well, your Honor, they marked it this morning and asked --

THE COURT: Solely to show it came from your files that you were aware of it. Remember that whole thing we had 22 on the screen and 5H and the hands and it was just pointing out that one had Bates stamp SEK and one had Bates stamp Hart, and his whole point was they were the same, and it shows that you had it in your files which you're going to check.

MS. HAGBERG: I --

THE COURT: That's all. He asked no substantive

questions about the 2007 or '08, that 510(k).

MS. HAGBERG: I understand that, your Honor. But the point of this document is to show that there -- the same concerns existed in 2007 that existed in 2009 and led to the withdrawal of the application. And that was something that Mr. Velie made a big deal of yesterday, that what were the reasons for withdrawing the 510(k).

THE COURT: Oh, yes. In 2010.

MS. HAGBERG: '10.

THE COURT: '09 or '10, but he didn't mention 2007.

MS. HAGBERG: But, your Honor, this document goes directly to that.

MR. VELIE: In that case, your Honor, this should have done it on the direct side so I have a fair chance. This is sandbagging.

THE COURT: It's not a problem with fair chance, because you can do recross. That's not an issue. I have the document on the screen. 93?

MS. HAGBERG: This is PTX-31.

THE COURT: 31, right. 31. This is -- no -- you were there then also, Mr. Fryer?

THE WITNESS: Yes, I was.

THE COURT: With the company?

THE WITNESS: Yes, I was.

THE COURT: But none of this is from you or to you?

THE WITNESS: No.

MS. HAGBERG: Your Honor, I'm offering this because Mr. Hart is making the same recognition that they could not proceed with a Femtelle 510(k) because they were missing clinical data, and that's same thing that he identified with the 2009. And it's the same reason why they felt they had to withdraw it, and that is my reason.

THE COURT: So basically you're offering Mr. Hart's statement, which is --

MS. HAGBERG: Yes.

THE COURT: -- a party opponent.

MS. HAGBERG: Exactly.

THE COURT: That's no problem. But to have him -- I don't know what question you're asking him yet. I don't know if that's going to be proper. The document can come in. It's a statement of Mr. Hart and it's relevant. And the only objection to it is that Mr. Velie thought you should use it on direct and not redirect, which is a very small point in this non-jury case. So I have no problem with your offering the document, which I will now read.

(Pause)

THE COURT: All right, I've read it. It's in evidence, but I'm not sure I'm going to allow any questions to this witness.

What's the question?

MS. HAGBERG: My question is if he sees the statement about the agency -- well, my first questions is whether this relates to Femtelle and if he can tell that?

THE COURT: I don't need him to tell me that. It does. It says so. I believe it said so. No question about it.

MS. HAGBERG: It refers to UPA and PAI-1, your Honor, which is the components of Femtelle.

THE COURT: Right, I have no trouble understanding that.

MS. HAGBERG: Okay.

And my question to him is is the statement that the reviewer of the pending 2007 application about missing line data --

THE COURT: Wait, wait. Where are you?

MS. HAGBERG: I'm at just today the agency reviewer --

THE COURT: I'm sorry, where are you, the first paragraph, the second, the first page? Where are you?

MS. HAGBERG: The end of the first paragraph.

THE COURT: The end of the first paragraph?

MS. HAGBERG: Just today?

THE COURT: I have not found you. The first paragraph of the first e-mail?

MS. HAGBERG: No. I'm sorry, your Honor, from the second Richard Hart to Mr. Smith.

THE COURT: Oh, okay.

MS. HAGBERG: Sorry.

THE COURT: "Just today, the agency reviewer requests that we urgently provide the following."

What's the question for this witness?

MS. HAGBERG: Is the line data for those three studies the same data that was relied on for the 2009 510(k)?

THE COURT: I'll allow that, because he's familiar with the 2009 510(k).

Is that the same material?

THE WITNESS: It is.

THE COURT: All right.

Q. And the problems that are identified in this PTX-31, about lacking the five data for the Harbeck Janicke and Zemzoum studies, the same issues that existed with respect to the 2009 510(k) Femtelle application?

A. Yes.

Q. Now, could you please turn to DX-GG? That was one of the documents that Mr. Velie gave to you yesterday?

THE COURT: Yesterday?

MS. HAGBERG: Yes, your Honor.

THE COURT: Just a minute. Now this disappeared from my pile. I don't have it.

MS. HAGBERG: I can give you a paper copy, your Honor, if that would be helpful.

THE COURT: I wonder why I don't have it, though? This is all material that for this witness. Oh, well. All right. I'll have to take it because I don't have it.

MS. HAGBERG: Your Honor, I don't know -- I think it is.

MR. WHITNEY: Your Honor, it should be available electronically.

THE COURT: That's why. I didn't bother. I just -- which one is it? What was the --

MS. HAGBERG: PTX-29, your Honor.

MR. WHITNEY: 29.

MS. HAGBERG: I have it on my little post-it.

THE COURT: Yes, I remember now. I didn't take it because I said I had it. Okay.

Q. Do you have a copy of that exhibit in front of you, Mr. Fryer? If not, I can give you another one.

A. I have it on the screen, but I don't have a paper copy.

MS. HAGBERG: Your Honor, may I approach just to --

THE COURT: If he has it on the screen, he's been working -- it's fine, but that's okay.

MS. HAGBERG: Only if --

Q. Do you recall this exhibit from yesterday, Mr. Fryer?

A. I do.

Q. And the top part Mr. Velie directed you to was a response in response to the discussion in your telephone conference that

had taken place, is that correct?
A. That's correct.
Q. I withdraw that.
What is the response that is shown in Monday, June 28, 2010 from Ms. Philip?
A. That we were getting very close to the end point at which the FDA would accept any further information from our company.
Q. And you see that she was still asking you for lot numbers about clinical studies?
A. Yes. And lost batch records as well.
Q. And was she also asking you about clinical validation studies?
A. Yes.
Q. And she's not suggesting here -- did you read this as suggesting that you did not need to have the information that she is asking about?
A. No.
Q. And where had the validation studies that she is referring to taken place?
A. They were took place in Germany and in Europe.
Q. And is that part of information that you were trying to obtain when you went to Germany in September of 2011?
A. I did.
Q. 2010. Excuse me.
And were you unsuccessful in getting that data?

A. I didn't make any headway, correct.
Q. You were also asked in connection with DX-GG, which is also PTX-29, whether it was correct that FDA had not yet responded to the ADI disclosure about the missing batch records. Do you remember that question?
A. I do.
Q. And you answered yes and said you wanted to clarify, that Mr. Velie said you could do that on Ms. Hagberg's time. What was the point that you wanted to clarify?
A. The point I wanted to clarify is that they had yet to receive an answer from their compliance officer from the FDA.
Q. And what did that mean?
A. That meant that the FDA had not yet determined whether the missing batch records were going to be a problem for our 510(k) submission.
Q. And even if the FDA had said no, would you have thought it was a problem, personally?
A. Yes, I would have.
Q. And why is that?
A. Because it was part of a larger -- all of the other problems that were -- that we had with the filing, that was yet another part of it. But traceability was I think the biggest issue for my own thinking.
Q. And, Mr. Fryer, as part of the analysis that you were doing on what steps the company should take with Femtelle, did you

prepare a time line and an estimate of the cost that it would require to get Femtelle to market?

A. I did.

Q. Do you remember how long you estimated it would take?

A. I believed it to be couple of years.

Q. And do you remember what your estimate of the cost was?

A. It was over three million I believe, two to three million or more.

MS. HAGBERG: Your Honor, may I have just a moment?

I have no further questions, your Honor.

THE COURT: All right, any recross?

MR. VELIE: Yes, there is, your Honor. However, they've introduced a new document. We just need to chase down the response to it, which will take us a moment, perhaps. Do we have it? Okay.

Your Honor, I am informed we don't have other copies, but what I'm going to do is put this on the Elmo.

THE COURT: Yes.

MR. VELIE: I hope everybody will be able to read it.

MS. BRILEY: It's plaintiff's exhibit 24, PTX-24.

RECROSS EXAMINATION

Q. Can you see it well enough, Mr. Fryer?

A. On the screen.

THE COURT: He's got it on the screen, right.

MS. HAGBERG: I've got it on that screen.

A. I do.

THE COURT: Well, he's got it, plaintiff's exhibit 24.

MR. VELIE: Right.

Q. You have it, okay. This is, is it not, FDA's comments on your 510(k) sent in May of 2009, which you actually commented on in plaintiff's exhibit I think it's 93, and I read out loud. You said these are minor, we can deal with them. Do you remember that?

A. I do.

Q. Okay. So this is the comment letter from the FDA, right?

A. Correct.

Q. Okay, let's talk about the line data. You've been talking to us about line data, right?

A. Yes.

Q. Wasn't the FDA's problem not that you didn't have the line data, but that you just didn't have it in an extractable format? Currently, the data is formatted as an image in a PDF document?

A. Can you, I'm sorry --the line data can -- may I read from this.

Q. Yes.

THE COURT: Well, that would be fine if I could find it too. Is that under -- I see the D is highlighted, but D is under what?

MR. VELIE: I'm sorry, it's on the second page of the

document and it's 2D.

THE COURT: 2D. All right. I'm there too.

"Please provide the line data of all three studies in an extractable format. Currently, the data is formatted as an image in a PDF document. Please explain the coding used in the line data; for example, the meaning of zero and one for tumor size, for age. Provide the exact age of patients.

Q. Is that what the FDA was having a problem with with your line data?

A. According to this.

Q. Yes, according to that?

A. Yes.

Q. Okay.

THE COURT: But this is the FDA's comments, right?

THE WITNESS: These are some of the FDA's comments.

THE COURT: Some of them.

Q. So that's what the FDA wanted, they wanted the same information in an extractable format; yes sir?

A. Yes.

Q. Thank you.

MR. VELIE: I'm not done yet.

BY MR. VELIE:

Q. With respect to batch records, do you recall which batch records were missing?

A. The ones that covered the clinical trials that pre -- I --

you know, I can't recall exactly what we had in-house, but there were many batch records that were missing for some of the studies.

Q. They were missing in a period approximately 12 to 20 years before the application, isn't that correct?

A. That's correct.

Q. And this old data had been lost in the move, isn't that correct?

A. We believed it to be so.

Q. Okay. Isn't that why the FDA was suggesting to you, it's lost, you lost it in the move? Please get us when you've got. And not only please get us when you've got, but they told you, you don't need to submit batch records to us, get the same information from your investigator and hold it in your files; isn't that what they said?

A. Yes.

MR. VELIE: That's it.

REDIRECT EXAMINATION

BY MS. HAGBERG:

MS. HAGBERG: Mr. Fisher, would you put up PTX-24 again?

THE COURT: Which one?

MS. HAGBERG: PTX 24, the FDA response to --

THE COURT: Okay.

MS. HAGBERG: -- Mr. Teicher of May 27th.

Q. In this particular request they're asking you for the batch records in a form that they could look at, is that right?

THE COURT: You're referring to the line data that --

MS. HAGBERG: The data, I'm sorry, the line data. Sorry, your Honor.

THE COURT: Okay.

A. Yes.

Q. And were there later responses that asked for additional information about the studies and the line data?

A. Yes, yes.

Q. And you didn't go to Germany to get a form of data that was extractable form, did you?

A. No.

Q. And could you clarify your response about what the FDA wanted when they were asking you for the batch records and saying that you could just have it in-house?

A. What they were asking for was the lot information that's associated with the patient.

Q. And did you have that information?

A. We did not.

MS. HAGBERG: I have no further questions.

THE COURT: Are you done with this witness?

MR. VELIE: Absolutely.

MS. HAGBERG: I'm done with this witness.

THE COURT: Then we were ready for the morning recess,

so we're going to take a ten minute recess and reconvene at ten of 12.

MS. HAGBERG: Thank you, your Honor.

THE COURT: Thank you.

THE WITNESS: Thank you.

(Recess)

(In open court, after the recess)

THE DEPUTY CLERK: All rise.

THE COURT: All right, the next witness.

MR. WHITNEY: Your Honor, just briefly before we begin. The parties conferred and wanted to clarify something that might be -- might make the testimony a little clearer going forward.

There were two applications for Femtelle that are at issue here. One was filed in I believe February of 2007 and another was filed in March of 2009. There has been some reference to 2008 application, but that's probably referring to 2007, but it's not. It's not a separate application. There is a 2007 and 2009. I thought that would just help your Honor get everything straight.

THE COURT: Okay. And the witness is?

MS. NOLEN: Timothy Ulatowski.

TIMOTHY ULATOWSKI,

called as a witness by the plaintiff,

having been duly sworn, testified as follows:

DIRECT EXAMINATION

BY MS. NOLEN:

Q. Mr. Ulatowski, what is your educational background?

A. I have a bachelor of science in micro biology from Penn State, a master of science in physiology with an emphasis in bio medical engineering from Georgetown Medical School.

Q. What did you do after college?

A. Well, after college I went to work at the Food and Drug Administration in Washington.

Q. How long did you work for the FDA?

A. Over 36 years.

THE COURT: Before we go on, are you Ms. Fleming or Ms. Nolen?

MS. NOLEN: I'm two last names, Fleming Nolen.

THE COURT: Oh, say it again?

MS. NOLEN: Fleming Nolen.

THE COURT: I'm sorry, I'm not catching the second part.

MS. NOLEN: N-o-l-e-n.

THE COURT: They didn't put that down.

MS. HAGBERG: It's easier for the Court. Sometimes it's clunky to say Fleming Nolen, but.

THE COURT: Well you should have put it on the sign in sheet. Now I know. Go ahead.

Q. How did your job responsibilities at the FDA change over

time?

A. Well, when I began at FDA I worked in a FDA laboratory in Washington, D.C. as a microbiologist for just a few years, about four years. And then I went to work in the office that evaluates new drugs, specifically arthritis drugs, cancer drugs and worked in that area for about three or four years. And then I went to the group that evaluates new medical devices and worked in that area and other areas in the device area until my retirement.

Q. When you refer to the area, can you say what specifically you're referring to?

A. Well, for medical devices the group that evaluates and manages and regulates medical devices is called the Center for Devices and Radiological Health in the Food and Drug Administration, and the CDRH, the acronym, consists of several offices that did various types of tasks related to medical devices.

Q. Did your work at the FDA include involvement with 510(k) premarket notification submission process?

A. Yes, for several years, from approximately when I joined the Device Center until 2003, I evaluated 510(k)'s and other submissions to FDA for clinical investigation of devices and other types of applications.

(Continued on next page)

Q. Were you involved with formulating FDA guidances and policies?

A. During my tenure at FDA, yes. Many guidance documents, policies, procedures related to premarket review, getting the product on to the market related to compliance and enforcement. Many different areas, yes.

Q. Were you on any committees?

A. Well, in FDA I was on many committees. I led several committees. Committees related to so-called standards program that was very important to the Center for Devices and Radiological Health. I worked on domestic and international standards committees and other international committees.

Q. Were you presented any awards during your time at the FDA?

A. I have three boxfuls in my basement. I guess a couple of hundred, maybe more.

Q. Can you point out any significant notable awards?

A. Well, distinguished service award at my retirement. Next highest award, I guess it's the FDA highest award. Beyond that is the award of merit, I received that. Commendable service awards. Group awards. Many, many different types of awards.

Q. About how many people at the FDA receive a merit award each year?

A. Award of merit? About a dozen, maybe half a dozen to a dozen per year.

Q. Are you involved in industry speaking engagements and

presentations to the industry?
A. As an FDA employee I gave numerous speeches at conferences, at professional associations, industry meetings, academia. As an employee of NSF International now I've given talks to various groups, academia, industry. I recently gave a training session to regulators in Southeast Asia on behalf of the Department of Commerce and FDA.
Q. And can you state your current employment and current title?
A. I'm currently an employee of NSF International which is a non-profit organization based in Ann Arbor, Michigan and my title is vice president for regulatory and compliance issues for medical devices.
Q. Have you ever testified at trial as an expert witness?
A. Yes, since my retirement, four times. This is my fifth.
Q. What was the general subject matter of your testimony?
A. Either related to submissions to FDA or compliance and enforcement issues typically.
Q. What were you asked to do in this case?
A. I was asked to look at records, the evidence concerning submissions made by ADI to FDA and documents related to those submissions.
Q. Did you focus on a particular product?
A. Yes. I was focusing on Femtelle, an IVD device submitted by ADI to FDA.

Q. Did you provide a report of your opinion?
A. Yes. I provided a report I think July of last year was the date of that report.
Q. What documents did you review in this connection?
A. The 510(k) submissions by ADI to FDA, the correspondence related to those submissions, e-mails and documents related to those submissions basically.
MS. NOLEN: Your Honor, I'd like to offer Mr. Ulatowski as an expert in medical device regulations, processes and procedures administered by the Food and Drug Administration.
MR. VELIE: No objection.
THE COURT: Okay.
Q. What role does the FDA play with regard to medical devices?
A. Well, FDA regulates the life cycle, so-called life cycle of a medical device from initial conception of the device by a company through its marketing phase and until its actually removed from the market for whatever reason.
Q. And which organization within the FDA regulates medical devices?
A. The Center for Devices and Radiological Health.
Q. Can I refer to that as CDRH?
A. That's the acronym, yes.
Q. How does CDRH obtain information on medical devices?
A. Well, by various means. CDRH inspects medical device

manufacturers, obtains marketing submissions from medical device manufacturers, obtains reports of death and serious injury related to devices from manufacturers and health care facilities, evaluates literature. FDA people attend conferences. Various, various means.

Q. What authority regulates medical devices?

A. Well, principally the Federal Food Drug and Cosmetic Act is the law under which FDA regulates medical devices and from the law are promulgated many regulations concerning medical devices.

Q. Are all medical devices subject to FDA regulations?

A. Yes.

Q. What is the framework for the FDA regulations?

A. Well, framework, I think basically the framework is, relates to what's called the classification process for medical devices. All devices are not created equal from a risk-based point of view. A tongue depressor doesn't have the same risk as an implanted heart valve. Congress recognizes that, FDA recognizes that, so devices are grouped into three groups or classes and the class into which a particular type of device is placed determines the regulations that apply to that device. So class 1, class 2, class 3 devices. Class 1 devices are typically low-risk devices. Class 2 device is moderate risk typically. Class 3 higher risk.

Q. What steps does a medical manufacturer have to take to be

able to sell a regulated medical device in the United States?
A. Well, unless you're exempt from the need to submit an application to FDA, which is the case for many class 1 devices and some class 2 devices, a manufacturer has to submit a marketing application to FDA and obtain FDA's clearance or approval depending on the type of application before it can proceed to the market.
Q. Can you explain -- you said clearance or approval depending on the type of application. Can you explain both types of applications?
A. Well, there's more than one way to get to the marketplace. But the two principal ways, application ways to get to the marketplace for a manufacturer is there's one method called 510(k) submissions, principally for class 2 devices. And the basis for a 510(k) submission is an evaluation of substantial equivalence of the new device to a legally marketed class 2 device. And so FDA, the application contains information upon which FDA determines whether the new device is equivalent. In doing so the new device is found to be as safe and effective as the legally marketed predicate device and then it's placed in class 2 if found equivalent.

The other method is for entirely new devices for which this equivalence cannot be employed. The device is evaluated for safety and effectiveness on its own merit. It's called a premarket approval application. Typically for, well, for class

3 devices, it's a requirement for that class.

Q. Does the FDA require clinical trials for 510(k) submissions?

A. Well, in general for 510(k) it's about 15 to 20 percent of 510(k)s will contain clinical studies. For IVDs clinical information is very important, so you'll see the percentage rate much higher for IVDs in regard to clinical data.

Q. By IVD do you mean in vitro diagnostic?

A. Yes, in vitro diagnostics, IVDs.

Q. Can you please describe for the Court what the FDA 510(k) review process entails?

A. The review process? The review process, an applicant submits a 510(k) to the FDA to the appropriate office. Administratively it's assigned to the correct branch within the appropriate office. The 510(k) is assigned to a primary evaluator for evaluation. That evaluator may rely upon any number of additional evaluators to provide input, comment on the submission.

Once the review has been completed the reviewer writes up a review document. That review document is looked at by management and decisions are made. Quite often the reviewer needs additional information and additional information is requested by the applicant.

Q. Who ultimately makes a decision to clear the device?

A. The division director of the specific division to which the

specific application is assigned makes that final determination. The decision can't be delegated to a branch chief but typically it's the division director.

Q. And you mentioned that sometimes the FDA does not have enough information to make the determination and they request additional information. Could you tell me what an additional information request is?

A. Right. When you receive a 510(k) and you begin to examine it you may find -- and I've evaluated hundreds of 510(k)s, you may find that there's information you need of any type in order to render a decision on that submission. And so you will compile the types of information you need. If there's other evaluators that are working with you on the submission they will likewise compile their questions and put it together, put it into an additional information letter, it's called, an AI letter.

Q. What happens if the information that the FDA requests is not submitted by the applicant?

A. Well, if the information requested in an AI letter, additional information letter is not provided, then the submission cannot proceed. It may well be withdrawn by the FDA or found not equivalent.

Q. Could you explain the difference between being withdrawn and not equivalent?

A. Well, the end result of a 510(k) review, the end decision

point is either a finding of equivalence of the new product to a legally marketed predicate so it's a substantial equivalence determination or the new product is found not substantially equivalent to the legally marketed predicate, in which case the new device is now class 3. Or FDA may determine that information is lacking and may withdraw the submission or request the applicant to withdraw the submission.

Q. Are there regulations in place that a manufacturer must consider in the 510(k) process?

A. Well, there's lots of regulations people have to comply with as far as a class 2 device in this case. There's the 510(k) regulation itself as far as how to submit, when to submit a 510(k) to FDA. There is the quality system regulation which is the overarching regulation concerning the design and manufacture of a device. There's medical device reporting regulations, there's labeling regulations, there's lots of regulations that have to be met.

Q. And you mentioned the quality system regulations for the design of the product. Can you explain more about that?

A. Well, the quality system regulation, as I've said, is a regulation that speaks to the design process for a medical device, and then the regulation moves into the requirements regarding manufacturing of the device, and actually also addresses the marketing of a device in terms of monitoring the device, in terms of complaints, in terms of problems that may

occur with the device during marketing. So it covers a life cycle of a medical device.

Q. So does complying with the design control requirements of the regulations include the design history file?

A. Part of the design control requirement in the quality system regulation is the need for the manufacturer to maintain a DHF, his own history file, yes.

Q. What is contained in the design history file?

A. All the activities related to the design process for a medical device; the design inputs, outputs that are described in the design control provisions as a regulation, so-called verification and validation testing, meetings concerning the design process. All those activities related to the design process.

Q. Would the design history file include batch records?

A. It will contain batch records related to the testing and evaluation of the product, yes.

Q. What is Femtelle?

A. Femtelle is an in vitro diagnostic device related, intended for breast cancer patients in terms of prognosis regarding those patients.

Q. Do you know if Femtelle is currently marketed in the United States?

A. I don't believe so. It might be under research use only, but that's a very, very, very restricted provision. But not

commercially available for clinical use, no.

MS. NOLEN: Your Honor, if it would be helpful to the Court we have two very basic kind of timeline slides that I think might be helpful. Is it okay if we put one up now?

THE COURT: That's fine.

Q. So this is regarding the 2007 application and the key dates. Mr. Ulatowski, when was the first 510(k) submission filed with the FDA?

A. It was in 2007, so it had this K07 number.

Q. Did you review ADI's 2007 510(k) submission?

A. Yes, I did.

Q. Could you please turn to PTX 22?

A. I have it.

Q. Is what has been marked as Exhibit PTX 22 the set of ADI documents relating to the 2007 510(k) submission that you reviewed?

A. Please repeat that?

Q. So Exhibit 22 in front of you, is that set of documents relating to the 2007 510(k) submission for Femtelle that you reviewed?

A. Yes, it is.

Q. Does this document contain only the submission?

A. This exhibit doesn't contain only the submission, no. There's additional e-mails, for example.

Q. And can you tell us where in the document the submission,

the actual submission starts?
A. Well, I considered it under Hart 0002495 to be the beginning of the document.
Q. Have you seen a similar document to this before?
A. Have I seen a similar document to this?
Q. When you were at FDA was this the cover page that's required for when you're filing a 510(k)?
A. At that point in time. This was the sort of administrative information up front.
Q. And can you kind of flip through the binder and let us know where it looks like the actual submission stops?
A. Well, it looks to me like 24543, looks like to me.
Q. So it looks like ADI submitted this in February 2007. Do you know if the FDA responded to this submission?
A. Yes, FDA did respond after its review with an additional information letter.
Q. Do you know if there was any other correspondence before the additional information letter?
A. There was some back and forth between ADI and FDA because the initial submission had contained an indication for use that would render the device to be a class 3 device and so there was back and forth about removing that particular indication so that a 510(k) would be legitimate for this product.
Q. And can you turn to the Bates number Hart 0024545 in this document?

A. I have it.
Q. Is this the back and forth that you were just referring to?
A. Yes, it is.
Q. And can you flip ahead to pages 2457?
A. 245 --
Q. 7.
A. Seven?
Q. It's also on your screen if that's easier for you.
A. You mean 47? 24547?
Q. 24547.
A. You said 2457.
Q. I apologize. In the middle of the page dated February 23, 2007 from Leigh Ayres to Reena Philip. Do you know who Leigh Ayres is?
A. She was at that time I think the regulatory and quality person at ADI.
Q. Do you know who Reena Philip is?
A. At that point in time she was probably branch chief in the FDA, the IVD group.
Q. In this e-mail Leigh Ayres writes --
MS. NOLEN: I want to kind of read the e-mail. Would you prefer me to read it, your Honor, or would you prefer to read?
THE COURT: You could go ahead.
Q. "Dear Reena: Attached please find the letter that was

prepared to withdraw the claim concerning prediction from the intended use statement and the attachments to that letter." Do you see that?

A. Yes.

Q. And can you explain what that means?

A. Well, that was one of the couple of claims that ADI had in the submission. And so as applicants will do, they'll attempt to remedy the concern of FDA by withdrawing claims or intended uses or indications for use.

Q. And you mentioned earlier that the FDA made a formal additional information request. Can you turn to Hart 00024552 in your binder?

A. I have it.

Q. And what is the date of this letter?

A. March 30, 2007.

Q. And so to make the record clear, the stamped date is the date that the letter was sent?

A. The stamped date is the date FDA stamps the letter and sent it to the applicant.

Q. And under, where it says re: K070422, there's two dates, dated February 7, 2007 and received February 13, 2007. What do those dates indicate?

A. "Dated" is the dates on the submission itself from the applicant. "Received" is the receipt date by FDA in its document control center.

Q. So what issues generally is the FDA raising in this additional information letter?

A. Well, they're covering pretty much the entire landscape of the submission from the indications for use to the clinical information that's been provided, analytical data that's been provided, product description. So -- caliber controls also. But these are a significant part of the submission. This is almost the entirety of the submission being critiqued by FDA and FDA asking questions about it.

Q. If we could go to the first page of this document, could you scroll back up? There's a number K070422. What does that mean? What does that refer to?

A. That's the number assigned by FDA. The K means 510(k). 07 is the year of submission and 0422 is the sequential number assigned to the 510(k) based upon receipt.

Q. Thank you. So could you please in this document on page 24553, where there is an E and then a little ii --

A. Yes, I see it.

Q. And it says, "Provide common clinical variables such as node status, stage of the disease, ER status, tumor size and grade, age of patient and menopausal status on datasets that are to be provided in Excel or text or SAS format." Can you explain what that means?

A. Well, FDA is asking for detailed information regarding studies that have been submitted. You can call these type of

data line data, source data, patient data, raw data. Whatever you call it, it's all the same thing. But this is what FDA is asking for.

Q. And under little iv on the same page, it says, "You must account for incomplete data in each study by providing an explanation for missing values." Can you explain what that means?

A. I think in every analysis of clinical data the data presentation has to be complete. Any information that's been not reported, any missing values may indicate bias, incomplete data collection by the investigators. Can mean a number of things.

Q. Why does the FDA ask for the raw data or the line data?

A. Well, the IVD group specifically more often than not like to have the raw data in order to conduct its own analyses of the information because historically FDA found that applicants may err in their analyses or may not focus in on important aspects. FDA had an interest in manipulating the data itself and that's why these requests were made.

Q. And can you flip the page to 24544? And under 3, analytical studies, can you explain the difference between an analytical study and a clinical study?

A. Well, basically analytical studies are studies with non-patient samples. They're substances obtained from animal cell lines and mice, goats, can be human cell lines but not

patient data and analytical studies are used to evaluate characteristics of the IVD; precision, accuracy, linearity of the tests. Very important parameters for an IVD.

Clinical studies, on the other hand, evaluate patient samples, patient information to assess clinical utility, ability of the test to provide clinically meaningful results to the clinician.

Q. And under 3A -- I'm sorry, under 3B on this page, limit of blank versus limit of detection. The FDA writes: "We believe you are referring limit of blank as limit of detection and suggest that you refer to CLSI document EP17 on the limit of detection. Provide data to support limit of detection and limit of quantitation."

Can you explain what that request means?

A. This is under analytical studies. FDA is asking for the raw data fundamentally and also referring to clinical laboratory standards in regard to this particular deficiency. It's important to know that IVDs rely heavily on clinical laboratory standards and in fact there's a guidance document related to this type of IVD and FDA refers to clinical laboratory standards for this type of device.

Q. And under 2C -- sorry, 3C, linearity study, the FDA writes, "Provide a detailed description of the linearity study such as type of sample used, how many samples, how many dilutions, how many replicates for each dilution, etc. Provide line data and

linearity curves." Can you explain that, please?

A. Again, as part of the analytical studies to evaluate the parameters of the IVD FDA is asking for the source data, raw data, line data, whatever term you might use in order to fully evaluate data and information being summarized by the applicant.

Q. Did ADI respond to this request for additional information?

A. Well, as applicants will do when they get a long and complex letter like this -- you'll note at the end of the letter there's a 30-day time frame to get the information in, but an applicant, any applicant can request an extension of time to respond to the additional information letter, up to 180 days, and I think ADI requested such an extension.

Q. Can you turn to page 24558 in this document?

A. Okay.

Q. Is this the request for extension you were referring to?

A. That relates to the extension, yes. Yes, it's a request.

Q. And do you know if the request was granted?

A. Yes. They're routinely granted, at least the first time around.

Q. And can you turn to 24560?

A. Okay.

Q. And what is this document?

A. This is FDA's acknowledgment of that extension. Extended until 26 September, 2007.

Q. And I see that from the date at the top where it says extended until --

A. Right, as I said, 26 September 2007.

Q. So after being granted the 180-day extension did ADI submit additional information to the FDA?

A. It responded to the AI letter, yes.

Q. Can you turn to page 24562 just behind tab 4 in your binder.

A. I have it.

Q. And then 24563, is this -- it appears to be another cover sheet. Can you read the FDA submission document number at the top?

A. It's the K070422.

Q. Is that the same one we saw before that's Femtelle?

A. That's correct.

Q. Can you turn to 24569, please?

A. Okay.

Q. And what is this document?

A. Well, this is ADI's I'll call it a cover description of the information provided in response to the AI letter.

Q. Did you review this response?

A. Yes, I did.

Q. Can you describe basically how ADI attempted to respond to the request?

A. Well, ADI does --

MR. VELIE: Excuse me. Your Honor, he may have reviewed the response but he didn't put anything about this in his report. Accordingly, this and many other things --

THE COURT: On this question objection sustained. I can't deal with "many other things." On this question objection sustained.

Q. Did the FDA consider this response to be sufficient?

A. No.

Q. And how do you know that?

A. Because FDA issued a second additional information letter.

Q. Do you know when the FDA issued the second additional information letter?

A. I think it was probably in November, as I recall.

Q. And can you turn to 24636 in your binder, please?

A. I have it.

Q. Can you tell us what this document is?

A. This is the second additional information letter issued by FDA on November 13, 2007.

Q. And can you explain what additional information the FDA is requesting?

MR. VELIE: Again, your Honor, I believe this is beyond the report.

MS. NOLEN: This is not beyond the report. There's a chart in the report that lists the different requests that the FDA made.

THE COURT: I'll allow it.

A. And the question is again, I'm sorry?

Q. Can you just kind of explain for the Court what the FDA is requesting, what additional information you're requesting?

A. Well, once again, you have to understand that when an applicant submits information, FDA reviews it, asks questions, applicants respond, FDA reviews the resubmission, may find different issues, may identify different questions. It's a rolling review FDA has. So FDA here has identified again clinical questions regarding the submission, questions regarding the analytical portion of the submission. So, which are I think two significant portions of an IVD submission.

Q. Where in the letter do you see the clinical questions, requests for clinical information?

A. Well, there's information actually related to number 1, number 2 asking for line data, number 3 relates to clinical studies, number 4 relates to package insert. But they're all related.

Q. And so for number 2, "In order for FDA to adequately review your submission we need to have the line data for the clinical studies from Harbeck 1992 and 2003, Janicke 2001 and Zemzoum 2003." Do you know what those three studies are, the three studies that are listed here?

A. Actually those are studies that were culled out from previous studies that the company had proffered, now looking

specifically at these principal three studies conducted in Germany, I think, to support the clinical utility of the product.

MR. VELIE: Your Honor, could we just ask the Court to read the next line?

THE COURT: I ask what?

MR. VELIE: That you read the next line after the yellow.

THE COURT: Yes. "The line data should be presented in a format that can be analyzed by FDA reviewers. You should provide the line data for the training set, test set and the independent clinical validation study. You should also provide the clinical protocol including inclusion/exclusion criteria, study design and statistical analysis with stated end points."

Q. Number three says, "Provide data to demonstrate prognostic markers, UPA PAI-1, provide additional information to the existing clinical equivalents." Could you explain what that means?

A. This is thinking about the utility of the product. What does this add to the options available to clinicians in order to treat cancer patients.

Q. And on the next page 24637, under number 5, analytical performance. Five D specifically says, "Linearity, limit of detection, hook effect studies: Please provide line data for these studies. Provide information on how you obtained the

blank sample for the limit of detection studies." Can you explain what kind of studies these are or what this means?

A. Well, again, they're analytical studies. FDA is asking for the raw data so it can do its own analyses of these particular types of studies. Linearity of the product, which evaluates concentrations versus outcomes, outputs; limited detections, which relates to the analyte, when the test would not detect analyte, for example.

Q. What did ADI do in response to this additional information letter?

A. Well, as with the other one, it's a pretty complex letter asking for a lot of data and information, and they're not going to be able to do it in 30 days. So they asked for an extension as they did before.

Q. And can you turn to 24640. And is this the extension request you were just referring to?

A. Yes.

Q. Turning to, looking at 24641, did the FDA grant that extension request?

A. Yes, until May 9, 2008.

Q. Do you know what ultimately happened to this application, this submission?

A. Ultimately?

Q. The 2007 Femtelle submission?

A. FDA ultimately withdrew it because of lack of response to

the additional information letter.

Q. Do you know if ADI made any efforts to obtain the information, the requested data that FDA was requesting?

MR. VELIE: Objection.

THE COURT: Sustained.

MS. NOLEN: I'm sorry, I'm not --

THE COURT: I sustained the objection. He can't know what was going on at ADI. He wasn't there. He just doesn't have the competence to answer that question.

Q. Did you review any correspondence where ADI was making efforts to obtain the data that's being requested by the FDA?

MR. VELIE: Again objection.

THE COURT: Sustained. He may have reviewed some, maybe not all. He's not in ADI. He can't testify to what ADI did or didn't do. It would be based solely on the records he did see, which we don't know if they're complete, so it's an answer that has no value. I can't give it any weight so I'm not going to take the answer.

Q. Do you know if ADI met again with the FDA or had any correspondence with the FDA after that November 13, 2007 additional information letter?

MR. VELIE: Again objection.

THE COURT: I'll allow that. A simple question. Do you know whether there was any additional correspondence. If you know.

A. Well, there was a meeting, discussion with ADI.

Q. Can you turn to 24643 in this document?

A. I have it.

Q. Is this the basis for your last answer, that there was a meeting?

A. Yes. It's ADI's minutes of that meeting with FDA.

Q. And can you turn to Hart 24647, please?

A. I have it.

Q. And the bottom e-mail is from Reena Philip again to Leigh Ayres? And it says, "Hi, Leigh. Janicke 2001 patient population also include ER plus patients. Could you please provide line data which shows how many of the low risk patient and high risk (no CMF treated) were tamoxifen treated? Please provide this information along with the survival data we discussed during teleconference."

Can you explain what information that Reena Philip is asking for?

A. Well, this goes beyond the AI letter. FDA has the opportunity at any point in time to ask for any information it needs in order to render a decision or evaluation of a submission and here Ms. Philip is asking for additional information of this type.

Q. Can you turn to 24649 in this document, please? Can you tell us what this document is?

A. The May 1, 2008 letter?

Q. What is the letter requesting?
A. Well, this is a request for an extension, another extension beyond the one they already have. That's basically what it is.
Q. And was this request granted?
A. I don't see -- no -- well, FDA withdrew the application so obviously it wasn't granted.
Q. And for the record can you just look at 24650? Can you explain this document?
A. This is the acknowledgment of withdrawal of the K070422 510(k).
Q. And based on your review of the 2007 application and correspondence with the FDA we just discussed, what did you conclude about the 2007 Femtelle 510(k) submission?
MR. VELIE: Objection.
THE COURT: I'm sorry?
MR. VELIE: Objection.
THE COURT: Let me read the question again. Is that not why he's here, to give his opinion on this very question?
MR. VELIE: No, your Honor. The sole opinion that he gave in his report, and this is important --
THE COURT: Yes. It all is important, it's always important.
MR. VELIE: The 2009, the 2009 application.
THE COURT: Is there nothing in the report about him reaching a conclusion about the 2007 submission, because if

there's not I'm not going to allow it.

MR. VELIE: He did not offer an opinion.

THE COURT: Let's be sure the plaintiff agrees.

MS. NOLEN: No. He didn't --

THE COURT: Show. Me, show me in his report in respect to the 2007 application. You asked him what did you conclude about the 2007 submission. I don't let experts go beyond their report. I'm very careful in every case and I say show me. Please point out where his report stated that opinion. Better yet, show it to Mr. Velie.

MR. VELIE: Perhaps I can help you, your Honor.

THE COURT: No, I don't think so. You need to talk to your adversary.

(Pause)

MS. NOLEN: In the beginning of his page for opinions he says, "Based on my analysis of these documents and information as well as my experience, knowledge and training, I have formed opinions with regard to the regulatory conduct of ADI and the 2007 and 2009 510(k) submissions for Femtelle."

THE COURT: And the opinion is? Where's the opinion?

MR. VELIE: The opinions are as follows --

THE COURT: I know you can point to what they are. I want her to be able to tell me where's the opinion about the 2007. He says he's formed them but if he doesn't disclose them in the report he can't disclose them for the first time on the

stand. Where is the opinion about the 2007?

MS. NOLEN: So he has, the opinion is broken into several places, your Honor, and on page 27 of his report --

THE COURT: Okay, well, why don't you go over that with Mr. Velie.

MS. NOLEN: Should I read it?

THE COURT: No. Go over it with him first. Maybe it will convince him that he gave an opinion.

MR. VELIE: Your Honor, we have a disagreement as to what the opinions are. It's in black and white and I can read it to you.

THE COURT: What's the page you want to cite to me? Let me know.

MS. NOLEN: Okay, so the first one, I'm sorry, that was the wrong page. On page 28, here, let me talk to --

(Pause)

MS. NOLEN: Your Honor, we disagree. Can I read the section into the record that I contend are opinions about the 2007 --

THE COURT: I think it would be best if you handed it up and showed it to me. I don't think it should be in the record if I'm not going to admit it.

MR. VELIE: May I --

THE COURT: No. I know what you're showing me. He has to state his opinion, 1, 2, 3. In the end he has to

disclose his opinion.

(Pause)

THE COURT: I don't see any opinion about the 2007. You can certainly bring out what's in the chart in terms of his observations but he gave no opinion similar to the question you just asked here at the trial. He obviously studied it, he wrote it up. He may have opinions as to what ADI should have anticipated on the next application but he gave no opinion in the end about what happened with the 2007 application, the 510(k) submission.

MS. NOLEN: Your Honor, can I -- your Honor, can I place the chart on the ELMO to ask him to discuss the observations?

THE COURT: Yes, sure. I should warn you lawyers I'm going to be taking a somewhat later lunch today, so I hope you're not too hungry because we're not going to stop at the usual time. I should have told you that earlier.

Q. Mr. Ulatowski, can you please explain this chart to the Court and what you were observing about the 2007 --

A. Could you pull it down just a little bit? I think there's a heading there somewhere. Well, this is -- I was looking at the deficiencies in the 2007 time frame, November 2007 time frame for that K07 submission, what were the issues at that point in time.

Q. And can you explain the issues under clinical and

analytical?
A. Yes. As detailed in the AI letter by FDA.
Q. I mean, can you briefly explain them now.
A. Well, I was looking at what I believe were significant, although there were many significant issues in that particular letter, but highlighting the data sets, the line data requests for the clinical studies, the data required for the analytical studies. So basically identified that there's some serious problems here in this, explained in the FDA November 2007 letter.
Q. And to your knowledge did ADI ever provide this requested information to the FDA?
A. No, they did not adequately respond to the AI letter.
Q. Did you also review ADI's 2009 Femtelle 510(k) submission?
A. Yes.
Q. Can you turn to PTX 23, please?
A. I have it.
Q. Is this the submission that you reviewed?
A. Right. This is the 2009, the first submission from ADI. It's formatted a little differently because it looked to me like it was related to an electronic submission format that the IVD group was using by this point in time.
Q. And can you turn to SEK 262804 in this document? It's the first page.
A. I have it.

Q. And there's a box that's called, titled indications for use. Can you explain what that box is supposed to tell the FDA?

A. Well, this is the disease conditions, the use of the product intended for the physician. So, and this is what this box contained.

Q. And if you go to the third kind of paragraph within the box, it starts with, "Based on clinical studies." Does that mean that this indication for use was dependent on the clinical studies?

A. Oh, very much so, yes.

Q. And then just below the box it says, "The prior submissions that are related to this release are as follows: None." Does that mean that this application is not related to the 2007 application you just looked at?

A. Well, once a 510(k) is withdrawn, as was the K07 submission, that submission is dead. It's dead. It's no longer in effect, it's no longer pending and so that's, ergo, the need for the K09 submission. So prior submissions related, none. I think that's accurate.

Q. And for your review, did you compare this submission to the 2007 submission?

A. I did. I did a comparison. I looked at principally clinical and analytical aspects of this new submission compared to the prior submission.

Q. And what did you conclude from your comparison?
A. Well, certainly ADI was re-presenting the information to the FDA, recalling the K07 document that they had focused in on certain clinical studies. They were asked analytical questions. They were trying to respond to those certain portions of the 510(k) clinical and analytical. So they submitted information concerning those aspects and all the other aspects as driven by the electronic submission format for the IVD group. They also included some additional references to additional guidance documents, standards. Additional references. So there was some additional information.
Q. Did the FDA send a response to ADI regarding the March 2009 submission?
A. Yes. FDA once again found the submission for Femtelle to be in need of additional information in order to render a final decision.
Q. And could you turn to PTX 24, please?
A. I have it.
Q. And what is the date of this letter?
A. May 27, 2009.
Q. Is this the additional information letter you were just referring to?
A. Yes. Yes.
Q. And can you generally explain what the FDA was asking for from ADI?

A. Once again a very detailed complex thorough review by FDA of that K09 submission addressing virtually every aspect of the submission, asking for re-presentations of data, asking for the raw data in several points in the letter. Very, very detailed complex letter of a type I think as complex as any I see at FDA in my valuations of 510(k)s that I conducted.

Q. And could you turn to within this document page, with the last three Bates number 053.

A. I have it.

Q. And under device description for A, it says, "The data used to validate your analytical and clinical claims should all originate from the version of the device that you intend to market. Please describe any substantive changes that have occurred with your device since commencement of studies and affirm that these changes are captured in QSR compliant design history file." Can you explain what that request means?

A. Well, first of all, the quality system regulations that I talked about earlier requires the use in validation studies of the product. That's intended to be marketed, or something very, very, very close to that product. So that's for any type of device.

And, secondly, the quality system regulation under design controls requires control of changes of a product during the design and evaluation phase of a product and not just substantive changes, but any change with the product during the

course of design and evaluation. It has to be captured under the quality system regulation requirements, in this case design history file in regard to the design of the product intended to be marketed.

Q. And 4D says, "Minimum tumor cell content. Please provide data to demonstrate the minimum amount of tumor cell content required to perform an acceptable assay." Could you explain that request, please?

A. Well, this relates to really instructions for use of the product. For adequate use of the product there needs to be a need for a particular amount of analyte to be used with the test so that's what this relates to.

Q. Did ADI respond to this request for additional information?

A. Well, ADI did provide a response as I recall it. I think initially another request for extension if I'm correct.

Q. And can you turn to PTX 25, please?

A. I have it.

Q. This e-mail is from David Teicher to Reena Philip dated Wednesday, November 4, 2009. Do you know who David Teicher is?

A. He is a technical affairs gentleman, something of that title, like that title.

Q. And in the first line it says, "Dear Reena, attached is our response to the deficiency letter dated May 27, 2009." Is this the response that you reviewed to that deficiency letter?

A. This is one response provided over the course of time, yes,

regarding that additional information letter.
Q. And if you just turn the page to the page ending 458, starting there, does this appear to be the attachment to that e-mail, the response that you reviewed?
A. Yeah. You know, I think this was Ms. Philip had received a resubmission and then contacted this David Teicher, if that's the pronunciation, asking for kind of the cover information for that submission because she couldn't figure out where it was in what was provided to her directly. So that's what this is here.
Q. And do you know if the FDA considered this response to be sufficient to deal with their concerns?
A. No. This was just one of a rolling set of requests by FDA for information.
Q. Can you turn to PTX 26, please?
A. I have it.
Q. Now, the second e-mail in the chain here is from Reena Philip to David Teicher dated January 15, 2010 and she says "Hi, David. Please find attached the review issues for K09711/S001." Do you recognize that K number?
A. That's the second submission for Femtelle, the one we're currently talking about.
Q. And if you turn the page to Bates number ending 938. Is this another additional information request from the FDA?
A. This is an additional information request, this being

transmitted by Ms. Philip to David Teicher in regard to that submission, yes.

Q. Can you generally describe what the FDA is requesting additional information about?

A. Well, as the FDA will do when you submit information, FDA finds more problems quite often, more questions. Again, the clinical analytical studies asking for more data, more information, to try and clarify what this test was all about and the basis for the safety and effectiveness of the test.

(Continued next page)

BY MS. NOLEN:

Q. And if you look at number two, clinical studies there, 2A, it says, "Your JC02002 paper and the followup paper by Harbeck, et al. provide data considered in your claim. You provided data for N=171 patients. We need clarification on the column that is labeled number of lymph nodes."

Can you explain what that request is?

A. Well, I think one issue here is that ADI is, I won't say in a negative way, but manipulating the data to try and find an adequate core data set for the clinical studies. Initially they began with a lot of patients in regard to the data set. Here they've reduced the number.

But in this data set there is missing values. There's values that are provided that are going to be problematic to FDA in regard to evaluation of the clinical data.

Q. And if you turn to 2C where it says, "It is unclear how you selected 171 patients out of 761 patients in the JC02002 study. Please clarify how you derived this number N=171 with respect to the numbers noted in table one of JC02002."

Is this what you were just referring to by the reduction in number of patients?

A. Yes, from the original data set. And, in fact, this number was going to be problematic later on too.

MR. VELIE: Objection. Your Honor, it's clear from what you saw he only opines that the 2009 510(k) would be

withdrawn, and it was proper to withdraw that.

He is not permitted, I believe, and I request a ruling on this, to speculate as to whether in the future there's going to be a problem for Femtelle. He gave no such opinion.

THE COURT: Right. You'd have to find that opinion for me, show it to me in the report, otherwise he can't testify as to his opinion point as to what would happen in a future application.

MS. NOLEN: I'm sorry, may I have a moment, your Honor?

THE COURT: Sure.

MS. NOLEN: Your Honor, would you like me to come up and show you?

THE COURT: Yes, yes -- well, actually show it first to Mr. Velie.

MR. VELIE: Your Honor, we have a disagreement. We believe that the sentence you're going to be shown is out of context. If you look at the opinion itself, it's opinion number one.

THE COURT: The sentence she's showing me in opinion number one?

MR. VELIE: Yes, it's in opinion number one.

THE COURT: Opinion -- well, it's their number, opinion number -- based upon the tables that were --

MR. VELIE: No. Opinion number one I believe begins

at page 24, opinions, and then number one.

THE COURT: Right opinion -- page 24, opinions, number one. "March 2009 Femtelle 510(k) submission was destined to fail due to insufficient clinical data and other documentation."

Then you want to show me sentence where? That's where you had it only -- the sentence that starts with what based on. She's showing me page 31, a sentence starting with the word based on which defense counsel argues is taken out of context, but I'll see what the sentence says.

MR. VELIE: Your Honor, if you read the next two sentences, you see he's --

THE COURT: I am of course.

MR. VELIE: Thank you.

THE COURT: I think this refers solely to the 2009 Femtelle 510(k). It is his summary of why he thinks it was destined to fail. He doesn't opine as to what would happen if it was submitted in 2013 or any other time. Just saying --

MS. NOLEN: Sorry. We don't submit that he does. We're not trying to have him say that. All we are we're asking about is whether or not the data would have been required, the data that was being asked for by the FDA would have been required for the Femtelle submission for this 2009 --

THE COURT: For the 2009, you can ask him that way. Be specific be. You can ask it, as long as you refer to the

2009.

BY MS. NOLEN:

Q. Okay. To be -- I'm not sure I know exactly where we left off. I think he had answered and there had been an objection.

But in 2B here, Mr. Ulatowski, please provide data to support that the test adds value over other clinical variables. Could you explain that for us?

MR. VELIE: Your Honor, this question should be limited as to the 2009 510(k).

THE COURT: Correct. I just said that. You have to phrase it that way. So rephrase it again, listen, see if you put in the words 2009. Go ahead.

Q. Okay. So can you please explain what 2B means in the context of the 2009 Femtelle submission?

A. In regard to the 2009 submission, this is a similar question previously raised by FDA about the utility of the product to the physician, in regard to other possible analytes and tests that are available.

Q. Okay, thank you. And do you know if ADI provided information to the FDA regarding the requests in this additional information letter?

A. FDA eventually did not obtain all the information that was requested. Beginning -- well, not just beginning, but including this, this particular correspondence -- well, it wasn't correspondence -- interaction with FDA at this point in

time, it was not completely provided.

Q. Could you turn to PTX-27, please?

A. I have it.

Q. And the top e-mail is from David Teicher to Robert Greenfield on February 19th, 2010. Do you know who Robert Greenfield is?

A. I think he was in R&D R&D chief as I recall.

Q. At ADI?

A. ADI, yes.

Q. And that e-mail below is from Reena Philip to David Teicher, discussing a telephone conference or, yeah, teleconference on the following Monday.

Was it common for FDA to have telephone conversations with people that submitted 510(k) applications?

A. Yes.

Q. Can you turn to exhibit 28, please?

A. 28? Okay.

Q. In the second e-mail on the page from Reena Philip to David Teicher, this is dated March 22nd, 2010. She says, "Hi, David. As per our teleconference about a month back, American Diagnostica was supposed to respond to the clinical questions which will give me an idea about whether you have --"

THE COURT: I don't want to remind you again -- this is why I took over the reading at the beginning of this trial, because lawyers cannot learn to read slowly. Please read it

slowly or I'll do the reading.

MS. NOLEN: Okay. I apologize, your Honor.

Q. "Hi, David. As per our teleconference about a month back, American Diagnostica was supposed to respond to the clinical questions which will give me an idea about whether you have sufficient data to pursue the 510 clearance, 510(K) clearance. I appreciate you respond back electronically with your response to clinical questions."

Did you review this e-mail when you were doing your expert report?

A. Yes, I saw this and the response by ADI.

Q. Okay. And is the -- the e-mail at the top, is that the cover e-mail for the response?

A. Yes.

Q. And if you look at within the same document at pages ending 804. Does this, does this appear to be the attachment to the e-mail of the response that ADI made?

A. Yes, with regard to 2009 submission, yes.

Q. And can you briefly tell us what this response consists of?

A. Well, this is ADI's response to the request for clinical information from that additional information interaction with FDA. Whether or not it was adequate was still subject to FDA's evaluation.

Q. Okay. And do you know if the FDA considered this to be adequate to clear the device?

MR. VELIE: Objection.

THE COURT: She said do you know. I mean, if he has that -- I don't know how he would know.

You're not there any more, right?

THE WITNESS: No.

THE COURT: Well, I don't think you should answer that question.

How much long other is the direct, just out of curiosity? Little bit longer? Okay.

MS. NOLEN: Little longer. Do you want to break?

THE COURT: Well, that's why I'm thinking. It's not a matter of, much a matter of when I break, it's when I can get back. I'm not sure of that.

MR. VELIE: Your Honor --

THE COURT: Yes.

MR. VELIE: Your Honor, I don't mean to constrict their opportunity to examine, but so far I have no cross-examination in view of your rulings, so if they finish we can send Mr. Ulatowski home.

THE COURT: I know, but I have an appointment I have to get to at a time specific. I'm supposed to be somewhere at exactly 1:30. I'm timing the minutes to walk that far.

So I don't think she's going to finish in three minutes, are you?

MS. NOLEN: No, your Honor. There is a few more

documents.

THE COURT: Right. So I think we need to break now. I just can't promise when I'll be back. So I think you have to be back, all of you, at 2:30, and I may or may not be here. I will try. So 2:30 is when we're reconvening.

MR. VELIE: Thank you, your Honor.

MS. NOLEN: Thank you.

(Luncheon recess)

A F T E R N O O N S E S S I O N

2:40 p.m.

THE DEPUTY CLERK: All rise.

THE COURT: All right, please be seated.

Q. Mr. Ulatowski, can you please turn to PTX-30?

A. 30.

Q. Yes.

A. All right.

Q. And I'm directing your attention to the second e-mail. There is a forward on top, but the second one from Reena Philip to David Teicher, and it's dated May 11th, 2010. Reena says, "Hi, David, I was willing to hear from you to send our additional comments as I indicated -- oh, I was waiting to hear from you, I apologize, to send our additional comments. As I indicated in my April 27th e-mail, please see the attachment for our comments to your March 26th response. Along with this, now you have three items to address: Review memo I sent to you

on January 15th. Precision reproduce ability issues which was sent to you on April 19th, today's comments in response to your March 26th response. Please send your response by the end of this month. So I will have enough time to finish everything by July 1st. Otherwise, we will be running short of time and you might have to resubmit another 510(k) with all this information."

Do you see that?

A. Yes.

Q. And did you rely on this e-mail in forming your opinion?

A. Yes, I did.

Q. And why?

A. It indicates at least at this point in time, May 11th, that there's a number of issues remaining outstanding regarding the 2009 submission that have to be provided to FDA in order for FDA to even begin their review of that data and to render a conclusion.

Q. Okay. And can you turn to page, the Bates number ending 677 of the same document?

A. I have it.

Q. And can you tell me what this is?

A. This is what she was referring to, at least one item she was referring to in her the memo we just looked at, where she talked about today's comments.

Q. And by "she" there, you mean Reena Philip?

A. Reena Philip from FDA, yes.

Q. Okay. And can you tell me generally what she's requesting in this attachment to the e-mail?

A. Well, she's asking about indications for use in terms of the product, asking for data in regard to the product, clarification of data already submitted. That's fundamentally what she's asking.

Q. And can you turn to page 674 of this same document?

A. 1674?

Q. Yes.

A. I have it.

Q. And the e-mail in the middle dollars of the page from Reena Philip to David Teicher dated April 13. 2010, she says: "Hi, David. Although I missed it during my review, I like to point out that you refer E-P-17 on page 18 of this document, bracket, document which you sent back in November, close bracket. Please note that we refer to E-P-five and not E-P-17 for precision reproducability studies.

Can you explain what that request means?

A. Well, I think I mentioned a little bit ago about standards that are used with clinical laboratory devices to protocols devise a testing for the IVD devices. And what Ms. Philip is referring to here are those standards, those NCCLS, National Committe for Clinical Laboratory Studies, standards, relating to what FDA believes are the standards that the company should

be using, test protocols should be using in providing information requested.

Q. Can you please turn to PTX-42?

A. I have it.

Q. Did you review on this document in forming your opinion?

A. Yes, I did.

Q. And can you tell me why you relied on this document or what you relied on it for?

A. Well, this is indicating still the need for data, the source data, line data, the background data for the studies that had been submitted. So this involves this Dr. Schmitt, ADI here, asking for original data necessary, because FDA's asking questions about that data, clarifying the data. And so they'll need it in order to get final decision from FDA.

Q. And in the third paragraph of this document Mr. Greenfield writes: "I hope that we can work this out ASAP, with a simple solution. We are in the end of the 510(k) process with the FDA and have already submitted the graphs and tables associated with 171 patients in the JC02002. If we can't supply the raw data for all of these patients, I am afraid that our application will be rejected because we can't produce the critical clinical data, which is the foundation for the clinical studies we have already submitted to them. FDA will surely ask us how we could submit the graphs and tables of the clinical studies without having the raw data behind the graphs

and tables. This will look very bad. We would not like to find ourselves in that situation.

Does the FDA, do you agree that it would look very bad or the FDA would consider it very bad if a company submitted summaries and tables but didn't have the background data?

A. Well, I agree with Mr. Greenfield here in his assessment. FDA is very very interested in -- with IVD's particularly, in the raw data. As I said before about doing their own assessments of that data, seeing the background data that's been summarized by in this case ADI, in regard to these patients. There's going to be some problems with these patients because of the lack of data.

And generally FDA wants to be assured that the applicant has, has the ability to obtain the raw data to verify that what's been submitted is, is truthful and accurate. So I think it's very important.

Q. Can you turn to PTX-43, please? Did you rely on this document in forming your opinion?

A. Yes, I did.

Q. And can you explain what this document shows?

A. Well, again, this is the ongoing attempts by ADI to obtain data that they've already summarized, presented to FDA in their application 2009 submission. And so they're still requesting this Dr. Schmitt from, in Germany, Professor Schmitt, involved in connection with the clinical studies. So again trying to

get the data.

Q. And in the third paragraph of Robert Greenfield's e-mail dated May 19th, 2010, he says, "It is quite possible that because of this the analysis will fail and we will have no JC02002 clinical study to present to the FDA that is valid. I cannot do anything about this. It if this happens the 510(k) will not move forward and we may have to abandon the project. Femtelle has a good chance of failing in the U.S. We may only be able to market it as an IVD in Europe under CE-marking. All this to say, if your present technical people can provide the missing data, please try."

MR. VELIE: Your Honor, of course this witness in May a month before they withdrew it is so speculating. However, I think we have a clear ruling that Mr. Ulatowski is not to opine along those lines.

THE COURT: Correct.

MS. NOLEN: Yes.

Q. So, Mr. Ulatowski, I'm not asking you to opine on Mr. Greenfield and what Mr. Greenfield meant. I'm asking you why you relied on this. Did you rely on the paragraph I just read in forming your opinion and why?

A. I think simply to further bolster what I had seen in other evidence that the submission was, was not going to be successful by the time that the review clock had expired.

Q. Okay. And can you turn to PTX-39, please?

A. I have it.
Q. Did you rely on this document in forming your opinion?
A. Yes, I did.
Q. And can you explain why?
A. Again, like, like the other documents, the attempts by ADI to obtain the data in order to provide information to FDA that was being requested. And this is just another document along those lines.
Q. And is there specific language that you have in mind when you say, when in providing with the opinion you just gave?
A. Well, I think this indicates not just lack of data, but where there might be, this is indicating lack of data where there isn't data, which is problematic of course in and of itself. We don't have information on certain of these patients. And if you have to strip away these patients from the analysis, then a reanalysis of that clinical study may not end up showing the same preclusions that ADI had demonstrated in the past or attempted to demonstrate, rather.
Q. And in the second paragraph where it says that you will get a final statement from us very soon regarding the 153 patients in focus of the FDA. Like I was saying, for some of the patients we do not have data, since these patients, according to our records, have not been assessed for UPA and PAI-1 at all.
Was that the basis of what you were just saying?

A. Yes, yes that's the basis for what I'm saying; that if, if the raw data did not clear the necessary data points, again like any study for any submission, then you have to start stripping away that data and reanalyze the data based upon what you do have.

Q. Can you turn to PTX-29, please?

A. 29?

Q. Yes.

A. All right, I have it.

Q. Okay. And the top e-mail is from Reena Philip to David Teicher dated June 28, 2010. Did you rely on this document in forming your opinion?

A. Yes, I did.

Q. And can you tell me why -- it's a long document, we're going to go through a couple of the e-mails in the chain -- but we can start with the top e-mail in the chain.

A. Well, this is now getting to the end of the review cycle.

In my opinion, as I expressed in my report, I think time was basically up for any kind of substantial review by FDA at this point in time anyhow.

And then, of course, ADI might have been faced with additional questions -- probably would have been faced, in my estimation.

And Ms. Philip is indicating the impending withdrawal of the 510(k) because they're at the end of the review cycle.

And then she raises this issue regarding the lot numbers for the clinical studies, just another question that's going to complicate the review process, still talking about 2009 submission.

Q. Can you explain what you mean by the that she raises the lot numbers?

A. Well, in regard to -- I mentioned this early on that, and it was in letters from FDA even -- I think the first letter FDA ever sent, was indicating the need to be able to verify products that were tested, what were -- what were the test articles. And things like batch numbers, lot numbers, other identifiers are important to indicate to FDA what exactly was tested. Because, again, as I said earlier, the quality system regulation demands that the product that's been validated is a product that you intend on marketing. So this is all part of that regulatory process and requirement.

Q. And where would that information normally preside in the company's records?

A. It could be in several places; design history records, device master record perhaps. Could be records from investigators that need to get into the source documents.

It's hard to say. I guess I'd be turning over all kinds of stones to try and find that information. But certainly it has to be in the history file, design history file.

Q. And can you turn in this document to the number that's last three Bates numbers are 199?

A. All right, I have it.

Q. So the middle of the page is the beginning of this e-mail from David Teicher to Reena Philip, dated May 28th, 2010. Do you recognize this e-mail?

A. Yes, I do.

Q. And did you rely on it in forming your opinion?

A. Yes.

Q. And can you explain why you relied on this e-mail or what you learned from it?

A. Well, partially this e-mail again talks about, at least May 28th, here we are getting near the end of the review of cycle ADI's attempts to respond to additional, the additional information request. And it also raises the issue in regard to batch record aspect referring to Jose Campo and his evaluation and the status of records at ADI.

Q. And in the third paragraph of this, on this page, it says, starting about four lines down, "We realize that batch records are an important component of the DHF. Unfortunately, we cannot recover the actual batch records as the kits used in the clinical studies were manufactured in the years 1997 to 1999. We produced -- presume that the records were lost during ADI's relocation from Greenwich Connecticut, to Stamford, Connecticut in 2003."

Can you explain the connection between the batch records and the clinical studies?

A. It's in regard to identifying the test articles, what was manufactured, when, how does it relate to the final product that's going to be marketed. So the importance of that identifying information is critical.

Q. And when you say identifying the test articles, do you mean -- can you explain what you mean by identifying the test articles?

A. Particular kits, components of the kits that were used in the tests that were conducted.

Q. So linking the components that were from ADI's manufacture to what was used in the clinical trials?

A. That's correct.

Q. So based on your review of the documents we've discussed today, what was your conclusion about the 2009 Femtelle 510(k) submission?

A. That the 2009 submission was not going to get cleared. They were far from a lot of information still outstanding, critical information, information that just wasn't yes no answer or dot the I's and cross the T's. Substantive information. There wasn't enough time for FDA to review even if ADI had submitted it.

In my experience, training reviewing hundreds of 510(k)'s, time was up. This, the 510(k) was not going to be

clear.

Q. And in your opinion or do you know what ultimately happened to this 510(k)?

A. Well, it was withdrawn by the applicant ultimately.

Q. And do you agree with that decision?

A. I agree with that decision. I don't think there was any other recourse, because as I said the time was up, the data wasn't there. It seemed to be an obvious choice. If I were management there, I would have made the same choice.

MS. NOLEN: I have no further questions, your Honor. Should we -- would you like to do the reading of exhibits now?

THE COURT: Sure.

MS. NOLEN: And I have a question about that. There are few documents that are business records. They're admissions that were relied on by Mr. Ulatowski but objected to here to be asked to him about, and I'm asking if we could move them into the record.

THE COURT: If they require a decision on my part and argument, I don't want to do it now. We can do it the end of the trial. Make a careful note to ask me and I'll hear why Mr. Velie opposes it, but I don't want to do it now.

MS. NOLEN: We've given him a list. I don't think they've opposed it.

THE COURT: I thought you said -- oh.

MS. NOLEN: We've given them the list -- they're

exhibits that we disclosed today --

THE COURT: Right.

MS. NOLEN: -- that we were going to ask Mr. Ulatowski about. We got no objection to them being admitted, but they were objected to being asked of Mr. Ulatowski.

THE COURT: Oh, I see. So --

MR. VELIE: I'm sorry, your Honor, I -- this is my fault. I apologize. I really can't answer right now. If we can spare this until I've had a chance to think about it, I appreciate it.

THE COURT: Fine. We can address it another time.

MS. NOLEN: Okay.

THE COURT: Now, is there any cross-examination?

MR. VELIE: There is no cross-examination, your Honor.

THE COURT: Okay, you're done.

THE WITNESS: Thank you, your Honor.

MS. NOLEN: I'm sorry, your Honor, but I didn't read the exhibits that --

THE COURT: You don't need the witness for that.

MS. NOLEN: Okay, thank you.

The exhibits are PTX 22, PTX-23, PTX-24, PTX-25, PTX-26, PTX-27, PTX-28, PTX-30, PTX-29, PTX-42, PTX-43, and PTX 39.

(Plaintiff's Exhibits 22 through 30 and 39, 42 and 43 received in evidence)

THE COURT: Okay. And the next witness?

MS. HAGBERG: Next witness, your Honor, plaintiffs call Bhavna Gaikwad.

THE COURT: What's the name?

MS. HAGBERG: Bhavna B-h-a-v-n-a, G-a-i-k-w-a-d. I think I misspoke.

THE COURT: He'll spell it when he gets here.

(Continued on next page)

BHAVNA GAIKWAD,

called as a witness by the Plaintiff,

having been duly sworn, testified as follows:

THE COURT: Please be seated. When you're seated, please state your full name, first name and last name, spelling both names for the record.

THE WITNESS: Bhavna Gaikwad. B-h-a-v-n-a, G-a-i-k-w-a-d.

MS. HAGBERG: Your Honor, I believe there are four exhibits that I wish to use to which the defendants have objected. Do you want me to address that now or would your Honor prefer to do it as I go? I think they're relatively straightforward.

THE COURT: Which ones are they? Are they in the notebook?

MS. HAGBERG: They are in the notebook. The witness hasn't looked at them yet. We gave them to them last night I think and we exchanged positions on them.

THE COURT: Which four are they?

MS. HAGBERG: The four are PTX 130 -- do you want all four at once?

THE COURT: Yes.

MS. HAGBERG: PTX 178, PTX 187, and PTX 202.

THE COURT: Are there different bases for the objections for each of these four?

MS. HAGBERG: They're out of time. I believe there are two to the relevant period two thereafter. The issue was there was --

THE COURT: I can't hear you. The issue was there was?

MR. VELIE: I'm sorry, your Honor.

THE COURT: I heard all of that up to was.

MR. VELIE: There was a compliance within the relevant period to 2006 to 2009, so stuff that happens before 2006 and stuff that happens after 2009 we believe is not relevant.

THE COURT: That may be, but these four exhibits may not be describing stuff that happens before and after. They just may be written particularly after, they were written after, they might describe, to use your words, "stuff" that occurred in the relevant period. The ones that are written before are not admissible, but the ones that are after I don't know.

MS. HAGBERG: Your Honor, the one that is after does refer back to an earlier e-mail but before the 2006 to 2009 time period. The three that are prior to the relevant time period all relate to a product that continued to be made during the relevant time period and they show issues that continue to exist --

THE COURT: In those exhibits they can't say the problem continued.

MS. HAGBERG: The witness can testify.

THE COURT: The witness can testify without the documents since those documents describe a time period prior to the relevant period. She can just say so, so I won't admit those three. The fourth one you said refers to a time before 2006?

MS. HAGBERG: The fourth one is after --

THE COURT: After 2009 but --

MS. HAGBERG: Well, let me back up. There's two that are after. One is after 2009. It's from 2010, it's an e-mail from Richard Hart to the several of the directors and it's basically supports testimony that she's going to give about conditions at the company.

THE COURT: From 2006 to 2009.

MS. HAGBERG: Right.

THE COURT: So that one's okay.

MS. HAGBERG: And the other one is an e-mail that she wrote in the 2004 time period and she forwarded it to the people who were working on bringing the company into compliance because it was still a problem. So it had been a problem all along.

THE COURT: I'm sorry. When did she forward it?

MS. HAGBERG: She forwarded it in 2010.

THE COURT: With a note, with a cover note?

MS. HAGBERG: With a cover note.

THE COURT: Does the cover note say something about this has been a continuing problem?

MR. VELIE: No, it doesn't.

MS. HAGBERG: And I believe, your Honor --

MR. VELIE: The answer to that is no, it doesn't.

THE COURT: There must have been a reason.

MS. HAGBERG: I believe, your Honor, the defendant also raised these as part of the cross of Mr. Fryer this morning.

THE COURT: You used the same exhibits?

MS. BRILEY: No, we didn't.

MR. VELIE: That's not correct.

THE COURT: I'm sorry, I'm lost. They said they didn't use them. Anyway, the two that predate 2006 the answer is no. One of the two that postdated I said yes already. So the only one is this second one that postdates where she forwards a 2004 e-mail in 2010. What does the cover note say?

MS. HAGBERG: The cover note says, "Dear Stephanie and Hugh: As per the discussion about our product 101201" --

THE COURT: Well, she can testify to that discussion being between 2006 and 2009. It all makes sense.

MS. HAGBERG: She's telling them about a product in 2010 that she had a problem with prior, prior to 2006 but is still a problem.

THE COURT: Yes, okay. As long as that's her

testimony I will allow both of the post ones and neither of the pre ones.

MS. HAGBERG: Your Honor on the one e-mail where I misspoke, the reason they used it in their -- by "they" I mean Hart's counsel -- they used in it their testimony this morning is they asked Mr. Fryer whether he had collected e-mails from a certain time period which was 2004 on and he said he did, he didn't know where they were, and we believe this is one of those e-mails.

THE COURT: That's not a basis to admit it.

MS. HAGBERG: Thank you, your Honor. Okay.

DIRECT EXAMINATION

BY MS. HAGBERG:

Q. Ms. Gaikwad, could you please tell us your educational employment background?

A. I have a masters in biochemistry and a masters in philosophy, a masters in philosophy in clinical biochemistry.

Q. And what is your employment background?

A. I can't hear you.

Q. I'm sorry. Let me back up. Do you have any experience in U.S. regulatory affairs?

A. Not till I joined ADI.

Q. And what is your employment background before you joined ADI?

A. I worked with two in vitro diagnostic companies back in

India for a total period of seven to eight years. I came to the United States, I worked as a visiting scientist in Loyola University in Chicago. I went back to the home country. I did another one year working with Gland Pharma company back in India and then I came back to the United States. I was hired by ADI in 2002.

Q. And how did you end up being hired by ADI?

A. I was sponsored as an H1B visa, so I was on a work visa hired by Richard Hart.

Q. And how did Richard Hart hear about you?

A. When I was working with Loyola University in Chicago, Dr. Farisi recommended my name to Richard Hart and that was how I was interviewed first in Chicago, I believe it was John Barryman had come to interview me and then they applied for my H1 visa.

Q. That was John Barryman?

A. The person who interviewed me, yes.

Q. I don't know if you said this or not but did you also work with Span Diagnostic?

A. I previously said I worked with two diagnostic companies. One was Piramal Diagnostics the other was Span Diagnostics.

Q. What was your job, your job responsibilities at Span Diagnostics?

A. I worked as a product development scientist. I was given a designation of R and D management. I was also overseeing QC

activities in the company at that time. I had six to eight people reporting to me, direct reports.

Q. And that job was at Span Diagnostics located in India, is that right?

A. That's right.

Q. Did you have to know anything about U.S. regulatory affairs in connection with that job?

A. We had our own regulations and not with the U.S., nothing to do with the U.S. regulations.

Q. I apologize if you mentioned this, but when were you hired at ADI?

A. April 2002.

Q. And what position were you hired for?

A. I was hired for QC specialist position.

Q. And what department were you in?

A. I was not given any particular department. I worked as a product development scientist. I was not directly associated with the R and D department at that time.

Q. So were you doing R and D type related work?

A. Yes.

Q. But you did not report to -- was Mr. Greenfield the head of R and D at the time you joined?

A. Yes.

Q. But you did not report to him?

A. Not at the time.

Q. Who did you report to?
A. I was asked to report to David Teicher.
Q. And anyone else?
A. No. For the first two years.
Q. And then what happened after the first two years?
A. After the first two years Richard Hart wanted me to report to him.
Q. And -- go ahead, sorry.
A. And I was promoted as a QC manager at that time.
Q. And what were your responsibilities as QC manager?
A. There were no written responsibilities given to me. I was not dealing directly anything the QC, I was still doing the projects which were assigned to me by Dr. Hart which was product development.
Q. So do you consider product development to be R and D research or what?
A. It's development, it's as a development part of R and D. It's not research, but it's a development part.
Q. Were you also making products in that time period?
A. I was not assigned to make any products.
Q. And how long did you have that job or title?
A. I had that title almost till Sekisui bought us.
Q. Who did you work the most closely with during the time period from 2004 when you were promoted to quality manager until 2009 or 2010, whenever, after the acquisition?

A. I was pretty much independent with my projects. I only worked for the projects which Richard Hart gave me. Typically what I used to do was once a project was given to me I used to complete the project and in between I used to let Richard know about the status of the project. At the end I used to write my report, I used to call a meeting with different departments and that's how we basically operated.

Q. And did you have any guidance from anyone in how you were supposed to develop the products?

A. No. Unfortunately, we did not have any kind of design control procedure at that time in place and obviously there was nothing like design inputs or design outputs or even a design plan to begin with. So having come from a background of assay development it was easy, it was okay, it was fine with me to develop the assays which were asked for me to do it, but as far as the documentation was concerned we never had that system in place.

Q. And were you told what forms to use at different stages of the product development or given any kinds of records to complete?

A. No. No. As far as I remember no, we did not have any research system in place.

Q. How many products was the company selling at the time that you were there?

A. There were many products, I believe it was more than 300

products.
Q. And was ADI selling FDA regulated products at the time that you joined?
A. Yes.
Q. Were you working in product development on products that were subject to FDA regulation?
A. Yes. I mean, typically usually the product was made as a research use only product and if the company felt that it has a good market then they would go for the IVD which is 510(k) application. So one of the products which I was, was the 101201 which eventually ended up getting the 510(k) certification.
Q. What kind of records did you keep of the product development work that you were doing, and let's take the 101201 as an example.
A. I used the lab notebooks. Most of the time we only used the lab notebooks to document as to what experiments were conducted and how the assay was developed.
Q. And when you say lab notebooks, what do you mean by that?
A. We had the lab notebooks which were given to us in which we used to record which had the project name, the date and you literally have to write in that as to what you were doing in terms of your development work. Again, there was no system in place. It was not hard and fast rule. Sometimes people wrote, sometimes people did not write. I mean, there was nothing like

somebody supervised that or was wanting, that the lab notebooks were looked at.

Q. Was a lab notebook like a blank notebook that you were given with the product name?

A. It was only the blank notebook.

Q. Did anyone come and do a quality check on what you were writing or what you were doing at each stage of product development?

A. No.

Q. And did you ever have to look for or reference other types of documents in the process of doing product development work for a particular product?

A. No. Like I said, we did not have any system in place. We did not fill up any forms or anything.

MR. VELIE: Can we fix some times here?

MS. HAGBERG: I believe that she's --

Q. Are you talking about during the time period from 2002 until after the Sekisui acquisition?

A. Yes.

Q. And after you had finished product development, what would happen with the developed product?

A. Once the assay is done --

Q. Let me withdraw that and ask a more preliminary question. What stage of a product did you take the product to in the work that you were doing in product development?

A. Typically -- can I give you a little background as to what --

Q. Yes.

A. So typically when an assay has to be developed what we do is we usually do a lot of search for the publications, look at what information is available as far as the literature is concerned. We start formulating each component according to what we know about different reaction types, different components, its characteristics. After that, you develop a formulation for each component.

You try to then put an assay procedure in place. What I mean by assay procedure is you start looking at the reaction characteristics of the assay. When you start finding out what incubation is required, what sample volumes are required, what region volumes are required. This is part of the product development assay development. This is what we typically do.

Once an assay is developed the most important thing in most of these individual assays is you have a standard whose concentration is known, whose purity is known, traceabilities is known. You use that standard and against that standard curve you then deduce the value of the plasma sample and that is how you find the concentration of the analyte from the standard curves. Once this whole process is done, what I typically used to do -- nobody told me what to do, but what I typically used to do was to run some kind of precision studies

to see that the assay is reproducible. What I mean by reproducible is every day if I'm doing, running the same assay, if I'm getting the same results, number one. We also look at plasma samples, normal samples as well as diseased plasma samples and make sure the assay is detecting normal levels and clinically significant levels.

After that, what I also used to do was some kind of reconstitute stability studies and acalytic stability studies. Now, this was not something that was told to me by working at ADI. This was the background and experience that I came with and that is how finally assays are developed. And once all those things are satisfied in terms of its performance then I used to write a project report and I used to call in a meeting with different departments.

Q. And who would you call a meeting -- did anyone ever look at the tests that you had run and the records that you had kept in your notebook for any products?

A. No. It was just the report which I believe, yes, I guess Richard had read it.

Q. Once you had gotten to the point where you were ready to hand it to manufacturing what did you do?

A. Typically what we used to do was --

Q. When you say used to do, what do you mean?

A. Since we did not have any design transfer procedure in place, R and D, I used to call myself as that part of that

group although I was not reporting to the R and D director, but, used to make the lots in R and D and then we used to get a manufacturing technician to work with us sometimes and they used to observe how we used to make, how I used to make a product.

We also need a lot of SOPs which are manufacturing SOPs, QC SOPs, laid out acceptance criteria, raw materials, vendors, qualified vendors for the raw material. But again like I said, since we did not have any procedure in place I used to put together an SOP sometimes if they asked for it and then manufacturing used to make the lots.

Q. And was there a design transfer process for you from if you had gotten a product to that stage where you would have a formal transfer of that product to manufacturing?

A. We did not have anything like that in place. We did not have a procedure in place.

Q. In the prior -- go ahead, I'm sorry.

A. So whenever a product has to be made by manufacturing they used to ask me the formulations which I used to give it to them and they used to basically make the product.

Q. And when you had previously worked in R and D was there a more formal process that was used to hand a product off from development to manufacturing?

A. Yes, in my previous company we did have a group of R and D scientists doing the design transfer process to the

manufacturing group.

Q. And what should happen in that step in your understanding?

A. Typically what we used to do was we used to make --

Q. You say we used to do. Would you just be careful to be clear about, are you talking before you came to ADI?

A. Yes, before I came to ADI what we used to do was whenever an assay was developed there used to be a validation of the assay taking place by doing the transfer process. When I mean a transfer process, that means we used to have forms where all the raw materials are listed down, the vendors or the suppliers for these raw materials they are listed down. Once the raw material, the vendor list has been given to manufacturing then they used to place an order for those materials. Meanwhile, R and D used to write the manufacturing SOPs in conjunction with -- in conjunction with the manufacturing technician. So there's a coordination, constant coordination which goes on within the R and D and the manufacturing division. QC person also comes in within that group, and the QC procedures are also being, you know, explained and discussed. So even before the design transfer what we used to have was --

Q. And again you're talking about before you joined ADI?

A. Back in India, before I joined ADI. What we also had was multiple meetings, so by the time the assay is developed almost everybody was aware of what needs to be done, there are documents in place. There used to be a procedure in place as

to how we would move ahead with this product in manufacturing.

So three lots usually is what used to manufacture back in India and once, if there are any deficiencies during the preparation of the lot or in the QC of the lot all those deviations or discrepancies are being brought up again in a meeting along with R and D group and we used to further discuss it to the extent where you do not have any deviations or any non-conformances once manufacturing starts selling the product, and then a full fledged validation used to take place.

Q. And in the products that you were working on in developing your position in R and D from the period from 2002 until the post acquisition time period, did ADI follow those procedures?

A. I don't think so. No, because obviously we did not have a design control procedure in place at that time.

Q. And when you would finish with product development -- you said you were making lots. What do you mean by that?

A. You make manufacturing lots, maybe 50 kits or a hundred kits worth of a lot. Suppose if I'm making it I'm making each and every formulation first is what I had done during my R and D work or development work. Then you get help from manufacturing either to dispense this formulated product in the vials. If it needs to be lyophilized it needs to go into the lyophilizer and needs to be lyophilized. And the packaging labels and package inserts and all those follow after the lot has been made.

Q. So the lot you were making, was that going out to the market?
A. Yes.
Q. And was anyone signing off on the forms that you were filling out and the documents that you were creating?
A. At this time, I do not remember as to this is, yeah, as to -- if somebody was filling up the form for me I don't know, but I did not fill up any forms.
Q. So you yourself did not create any forms with respect to the work you were doing in making lots and turning them over to be lyophilized and then sold to the market?
A. No.
Q. And is that only RUO products, research use only products that you're talking about?
A. Yes. I mean initially we started off in the research use only products.
Q. And did there come a time when you were working on products that were intended to be IVD products?
A. I did not make any manufacturing lots for IVD products.
Q. Did you work on development for an IVD product?
A. Yes, the 101201 was one of them and I also worked on Femtelle.
Q. Did you run into any problems with working on the development of lot 101201?
A. The initial part, when the development work was over and

certain SOPs or certain, you know, documentation was given to manufacturing --

MR. VELIE: Excuse me, can we just fix a time for when she began working on 101201?

MS. HAGBERG: May I show her the document just to refresh her recollection?

THE COURT: I don't know if she needs it. When did you start working on that product 101201? When did you start working on that?

THE WITNESS: I started working I believe in 2003, 2004 at computing the assay tentatively. I don't remember the exact dates.

MR. VELIE: Excuse me, your Honor, this then is outside our period.

THE COURT: She said she began working on it. She didn't say she finished working on it.

MR. VELIE: She said she finished in 2004.

THE COURT: Did you say that?

THE WITNESS: I finished working, the assay was developed in 2004, conclusion.

Q. When you say you finished working on it, though, what happened?

A. Well, after that it went to manufacturing for preparation of the lots.

Q. Were you taken off the project, Mrs. Gaikwad?

A. That was when manufacturing decided that a 510(k) has to be -- that they were moving ahead for the 510(k) yes. There was a precision study which we started, I don't remember the exact year, and at that time I was asked to do the initial, to start the precision for this assay. The first time when I did it, I realized a couple of experiments, one or two runs when I did it, I realized that the assay was not performing as what it was passed on a year before. I was asked to continue to do the runs, to do the experiments because the project manager found out it's too, the data is not enough to say that it's not performing the way it was supposed to do. So I ran another five days the same assay and then I had to send an e-mail to Richard Hart saying I have a concern about this product, it's no longer the same product as what was developed.

MR. VELIE: Your Honor, may we precise that date? That's 2004.

MS. HAGBERG: But your Honor didn't say she couldn't testify about it.

MR. VELIE: But let's make sure what's being said here.

MS. HAGBERG: I think she said that was in 2004.

Q. When was that, Mrs. Gaikwad?

A. That was in 2004 when we applied for the 510(k) application.

Q. Was the 510(k) application granted?

A. I was removed from the team. I do not know as to what happened after that.

Q. Do you know if the product ever got 510(k) cleared?

A. Yes, with regard to 510(k) cleared, yes.

THE COURT: What did you say? Yes what?

THE WITNESS: The product got the 510(k) clearance.

Q. Do you know when it got the 510(k) clearance?

A. I don't remember the exact dates.

Q. Was it still on the market in 2010?

A. Yes. Yes, it was before 2010.

Q. So it went on the market sometime after 2004 and was still on the market in 2010, is that correct?

A. Correct.

Q. So when you said that you had a problem with it, when you had a problem with a product, what would you do? In the 2004 on period, and talking about product 101201.

A. Well, with respect to this 101201 product, like I said earlier, that since I had some concerns I sent an e-mail to Richard Hart since I was reporting to him of course and I don't think anything was done with respect to remediating those problems. The vendor had for the 510(k) application many ways, but I was not part of the 510(k) process anymore, so --

Q. May I ask the witness to look at Exhibit 178 and, your Honor, this is the 2010 document that includes, that forwards the 2004 e-mail from Ms. Gaikwad to Dr. Hart. Let's start at

the top of the document, Ms. Gaikwad. First of all, do you recognize this document, the plaintiffs PTX 178?

A. Yes.

Q. And what is it?

A. So this was when we started the remediation effort and realized that the product still has the issues with respect to 101201. I was trying to give a scientific brief explanation as to what I had observed in the year 2004 once Stephanie and Hugh started working on it. I just wanted to give them the background as to what they should be looking at because of the issues which we were having.

Q. And were you working on remediation for product 101201 as to this time period?

A. Once this 2010 -- once I took this project on line, yes, I was part of the team.

Q. And so this -- so what are you doing with this e-mail? I'm sorry, could you just explain again because I wanted to make it clear that you were working on this product. What were the problems with 101201?

A. Typically there was a component which is called a tPA standard in the product, and sometimes when I started -- when I did the development work, the tPA standard which we were using as a native protein during the relevant work got changed to a recombinant protein sometimes. I'm not aware of when these changes were.

Q. Could you explain what you mean by it changed to a recombinant protein?

A. Recombinant protein is the protein that is made in the bacteria. The mix changes. It begins as a native tPA, but the source of the protein changes. Native tPA we used to get from the plasma or other sources, but this one was genetically developed.

So my concern was because we changed the source of the tPA standard making that is why we're having issues with this product, was one of my e-mails which is here below in 2004. I wanted the two scientists, Stephanie and Hugh, to look at this explanation and see if tPA standard was a problem and do some experiments to figure that out. Unfortunately, when the standard was changed from native to recombinant we did not carry any validation experiment so validation study was not done at that time, and what we then did in 2010 was we definitely did make sure that the standard was made correctly and, you know, labeled correctly on the vial.

Q. So at some point in time during the history of the product this standard was changed and there was no record of that, is that what you're saying?

A. I'm sorry, what?

Q. I'm just trying to understand, could you just repeat what the problem was? That the product, there was a change that was not validated and not in the records. Could you just explain

again what the problem was?

MR. VELIE: Can we find out the basis of her knowledge of this, if any?

THE COURT: Sure.

MS. HAGBERG: If you would allow me, your Honor, it's explained in detail in I think in the e-mail that is below the 2010 one, she explains what the problem is.

Q. Was this based on your own work?

A. Yes.

Q. And what was the problem that was discovered in 2010?

A. The tPA standard activity which was given on the vial label was not -- we did not, we never used to test that activity. Therefore we had to make some procedural changes to the SOP which was -- which manufacturing used to use and we also made some procedural changes to the stock tPA which we get from the vendor.

Q. And that was the remediation that you were doing?

A. Correct.

Q. Were you doing this work to remediate the product?

A. Stephanie was doing the work, was reporting to me at that time to do this work.

Q. And did Stephanie or Hugh go back to see if you could find the records in manufacturing that would tell you what changes were made?

A. We tried to look at as many records as possible. There was

information which was given which we could gather out of it was that, number one, there was no procedure to first find out the activity of tPA which should have been carried out routinely before bringing it in the vial. We used to label the tPA standard as 6,000 units on the vial but we were not sure that it was 6,000 units or not. So there was therefore as R and D group what we did was we put a procedure in place to figure out first what the activity is, make sure that the activity is 6,000 units on the vial and then put it out in the kit.

Q. So what you're saying is the information that appeared on the label on the vial was not backed up in any document that you could find?

A. Yes. There was no data to support that it was 6,000 units.

Q. And so you went back and did testing to see if that was accurate or not?

A. Correct.

Q. And did you determine that it was accurate?

A. The activity was pretty low in many vials, most of the vials.

Q. And what does that mean that the activity was low?

A. So the activity is low this is the standard which tells you whether you would pass your acceptance criteria. Our acceptance criteria for this particular standard is that the optical density should be greater than .9 at a certain wavelength. And what we observed was if the standard was not

correctly labeled or if it was not 40 units, because from 6,000 units you have to dilute the standard to 40 units in the kit, that's what is the kit procedure is concerned. So the 40 unit of standard if it is not 40, then you would not get the optical density of .9 or greater.

Q. And what would happen if you had the wrong optical density?

A. In this particular assay, the major issue would have been that your patient plasma sample readings would get affected. Like I mentioned earlier, as part of the assay procedure you always have a standard curve which has to be accurate enough that when you deduce the readings of your patient samples from this standard curve they should be reading correctly.

Q. And what would be the result if it wasn't reading correctly?

A. You would have a sensitivity at the lower end of the assay. That means between 10 to 20 percent, 10 to 20 in case units per ML. In this particular assay if your standard curve is not within your specification, which is greater than .9, then your samples which are at the lower level of the curve might not read accurately.

Q. And does that mean that the kit would not do what it was supposed to do?

A. I would think so, because we also give, we put some claims in our package insert for the limit of detection, I believe, and, you know, those claims may not be true then.

Q. And when you pointed this out to Dr. Hart in December 13, 2004, was this the problem that you were identifying back in 2004?

A. Yes. Because this was part of my, the 510(k) work which I was put to carry out this work and I was having concerns with this product and therefore since I had done the development work on this product I pretty much knew exactly what the problem was, yes.

Q. And in your 2004 e-mail you stated, "It is my candid opinion that this change in the kit's specifications has been made through an incomplete understanding of the technical aspects or negligence." What did you base that opinion on?

A. That was exactly -- I was trying to talk about the standard. In my first paragraph if you look at, I'm saying that the 40 unit of the standard should have been reading greater than .9 but it is now showing .8 or less than that sometimes.

Q. And was your concern that the product wouldn't work in the way it was supposed to work?

A. Correct, because I ran normal plasma samples during this experiment or after this experiment and what I see is all these plasma samples are reading below the detection limit of the assay. It means that on the instrument it is saying not defined, which means it is reading below the zero units.

Q. And could you look at the last paragraph of PTX 178 that

appears at SEK 882, that's the page in the bottom right-hand corner. It's the second page of your e-mail. And it says, "I understand that we are selling this kit with minimal customer complaints. It is also clear that our control plasmas, the lowest one of which has PAI equals 16.8 plus or minus 3.7 IU milliliters has a wide range, will not reveal this problem. I think this issue needs to be urgently addressed before proceeding with further 510(k) testing."

Did you ask Mr. Hart what you should do about this?

A. Yes. I mean, I did send the e-mail detailing about what technical aspects of this issues were.

Q. And did you get a response from Mr. Hart to this e-mail?

A. I did not get the response from Dr. Hart about this e-mail, but we had a meeting with the project manager and the person who was the clinical trials manager, they decided that a new lot of kit would be used and scrub this lot.

Q. And what happened to your involvement in this project?

A. So after that I was removed from the team of course.

Q. And in 2010 when you began working on issues related to 101201 again did the same problems remain?

A. We remediated the problem by putting a procedure in place to, number one, estimate the tPA standard activity and label according to what your test results.

Q. My question was a little different. In 2010 when the remediation was going on, was 101201 having the same problems

at that time before you remediated that are described in your 2004 e-mail?

A. Yes. We were seeing a low OD. What happens typically, and by doing a QC off the new lot an approved lot is always taken as part of the QC procedure. And it is run side by side. And what we were seeing was that the approved lot was also showing an OD of less than .9 at the time. That means it was not passing within the specification.

Q. And that was the same problem that you had back in 2004, is that right?

A. 2004 also we had -- 2004 I was doing the 510(k) work. So these are the different experiments. So this is when I was actually running the assay from the lot which was selected to do the 510(k) work. That lot was also even with .8, the OD's were going down and therefore I had a concern about that.

Q. And was this the only problem back in -- when you would have a problem with a product that you were working on, what would you do? Who would you report to?

A. I would typically I would send an e-mail to Richard Hart, yes.

Q. Did Richard Hart come and talk to you in response to any of the e-mails that you sent him?

A. Yes. I mean, intermittently yes. He used to come and tell me as to what we can do in order to correct them or in order to do some -- it used to be very, very minimal interaction.

Q. And were there any forms created at the time to document any changes and did anyone sign off on those forms?
A. No. We had -- no. We did not, not -- there were very, very inadequate documents which used to be there, yes, and yes, I mean, some of the documents used to be signed off. I don't know what the criteria was as to what documents should be written and what should be sent out for the reviews.
Q. Do you think you should have known what the criteria was for documents that were supposed to be kept and approved?
A. I think so, yes. I mean, it was not part of the system and there was nobody who one could ask as to what should be done and how it should be done.
Q. Again, what time period are you talking about?
A. This is from the time I joined ADI until almost 2009.
Q. And did there come a time when someone was hired as QA RA director?
A. Yes, Leigh Ayres.
Q. And when was she hired?
A. I believe it was 2004.
Q. And did Ms. Ayres make a difference in how the procedures were run or how products were developed and the change to manufacturing?
A. Ayres was, I mean yeah, she tried. She tried a lot at this place. Myself and one of my colleagues really wanted to help her out because we wanted some kind of a system in place. We

really wanted that the company should have some kind of compliance in terms of design control or some kind of, you know, manufacturing and QC the way things were based on that. But I'm sorry to say that nobody listened to her at all. As a result, again, I'm not sure why, but there were all the documents were in written form, but the implementation part was lacking at every stage.

Q. And who was your colleague who you said you were working with to try to support Ms. Ayres?

A. Enri Guinto.

Q. I'd like to direct your attention to 187, PTX 187, please? Does this reflect how things were carried out during your time at the company from 2002 to 2009?

A. Yes. This is very typical of what used to happen, yes.

Q. And what do you read Mr. Hart to be saying?

A. Well, in this particular e-mail it says that the 885, product number 885, which is a VWF activity kit to which we had a technology transfer from another company, unfortunately we were not able to make it the way the specifications were laid out for this product by another company. As a result we were having issues with the 8825 in terms of its performance and what this e-mail is telling me is that although the kit is not perfect or sufficiently perfect, just find out how you can make it perfect, I believe.

Q. And in the meantime, what does he mean please keep this

troubled product in stock?

MR. VELIE: Excuse me.

A. Well, that means --

MR. VELIE: Excuse me. This is speculation on what Richard Hart it is saying.

THE COURT: Sustained. That's a correct objection. She can't interpret what somebody else is saying.

Q. Is the way of doing business that is expressed in 187 consistent with how things ran at the company during 2002 and 2009?

MR. VELIE: Objection.

THE COURT: That one I will allow.

MR. VELIE: It's been asked and answered.

THE COURT: It may be. I'll just allow it. It's faster.

MS. HAGBERG: Could you reread the question for me?

THE COURT: Now it's not fast. Your objection is sustained. I'm sorry, we need to move on. It was a very minor question in the first place. All right, let's go.

MS. HAGBERG: Your Honor, I would just request again that I be permitted to introduce PTX 130 and PTX 202.

THE COURT: Those were the ones from 2004?

MS. HAGBERG: They are from 2004.

THE COURT: I already said no. I'm not revisiting any rulings. We need to move on. We're ending Wednesday and we've

gotten about five witnesses out of what I'm told is 18. This is not a good sign. We may not finish this until June, I have no idea. I allotted the time you folks predicted but it's moving very slow.

MS. HAGBERG: I have no further questions for Ms. Gaikwad.

THE COURT: Thank you. Thank you. All right, cross-examination, Mr. Velie?

CROSS-EXAMINATION

BY MR. VELIE:

Q. Ms. Gaikwad, maybe I can straighten out a few things while we're looking at some documents. Your basic function was to be working in R and D, is that correct?

A. Assay development.

Q. Assay development. So the things that you were making, if you were making anything, were research use only?

A. For 101201, 846, yes.

Q. And generally speaking when you were actually making kits, you, yourself, it was for research use only, is that correct? That's what you told us?

A. Correct.

Q. Okay. And research use only means it's not going to be sold to anybody, isn't that correct?

A. No, it is still a sellable product.

Q. But it's plainly stated research use only and can be sold

for research use, is that right?
A. I'm not sure about that.
Q. Okay. And you're not here to testify as to FDA regs --
A. Correct.
Q. About research use, correct?
A. That's true. I do not know.
Q. Before it could be sold commercially so that people can actually use it diagnostically, right, these kits need to get FDA clearance through the 510(k) process, isn't that correct?
A. For a 510(k) product, yes.
Q. And I think you testified that many of the products that you did which you worked on for research use actually got 510(k) clearance, is that correct?
A. 101201 was one of them.
Q. Is it correct that many of the products you worked on in fact got 510(k) clearance.
A. No, that's not correct. Because --
Q. So --
A. I don't believe I worked on any other product other than 101201 which were 510(k).
Q. Okay. And 101201 got 510(k) approval?
A. Yes.
Q. And I think you talked about what you thought were problems in reporting data in lab notebooks as opposed to in some other fashion, is that correct?

A. I didn't understand the question.
Q. Did you talk to us about lab notebooks?
A. That is how I put my data in the lab notebooks, yes.
Q. And to the extent that any product that you worked on got 510(k) clearance, those lab notebooks were sufficient for the FDA, weren't they?
A. I don't know.
Q. Now, I believe you've told us, and I'd like you to confirm it, that you did not work in manufacturing at all.
A. No.
Q. No, you did not work in manufacturing?
A. I did not work in manufacturing.
Q. You told us I believe in connection with the 101201 kit in 2004 you sent something to Dr. Hart and didn't get a response?
A. Yes, I did not get a response.
Q. Okay. I want you to look --
MR. VELIE: We're going to have to put this on the screen, your Honor, because to some extent we're a little bit surprised by this testimony. Can we see it at the bottom, please, who is copied on this?
Q. Did you receive a copy of this document, Ms. Gaikwad?
A. Maybe. I do not remember.
Q. You don't remember getting a copy. Okay. Does this indicate that you did get a copy?
A. Probably.

Q. Probably.
A. Since my name is written.
Q. And what Mr. Hart is saying here is Bhavna has reported to me --
MR. WHITNEY: Your Honor, we don't have a copy of this document.
MS. BRILEY: Our hard copy is on the screen.
MR. WHITNEY: It's going up and down.
MR. VELIE: It's going up and down to show she was copied on it.
THE COURT: Do your best.
MS. BRILEY: I don't have the hard copy anymore.
THE COURT: Do your best. She'll give it to you when she can.
Q. "Bhavna has reported to me as is her responsibility for QC that she has major concern about the range and sensitivity of our spectrolyzed PPA PAI-1 activity assay in its current form." That is exactly what you were complaining about, right?
A. I am, yes. I'm looking at it carefully. Why was this not CC'd to me in terms of --
THE COURT: It was.
Q. It was CC'd to you?
THE COURT: It says copied. See your name at the bottom? See your name?
THE WITNESS: I do see my name, but I don't remember

receiving it.

THE COURT: You don't remember. It was ten years ago so it's not surprising you don't remember ten years ago. But in any event it says you're copied. So let's continue.

Q. Your memory is not perfect of events that happened ten years ago, correct?

MS. HAGBERG: Objection, your Honor.

THE COURT: Perfect? Nobody's memory is perfect of events that occurred ten years ago, nobody. I take judicial notice of that.

Q. Her analysis and findings are attached in the report. Let's take a look at your e-mail to Richard Hart of December 13, 2004. That was your e-mail, right?

A. Yes.

Q. So this was in fact sent on to Clare Santulli. Who was that?

THE COURT: Do you remember?

A. She was working in manufacturing.

Q. And David Teicher?

A. Yes, he was the project manager.

Q. "As I find her concern and explanation plausible and the claimed differences substantial notwithstanding lack of customer complaint, I require that we together consider the situation as reported and to follow a possible course of remedy as and if so indicated. Please consider these matters as soon

as possible and arrange a meeting on the subject, but not during December 16 or 17 or 22 and 23, 2004 when I am with visitors then at AD Canada/QPR. Thank you. Sincerely, Rich Hart," which is Dr. Richard Hart, isn't it?

A. Yes.

Q. Now, do you recall other times when you complained to Dr. Hart and you contend that he didn't respond to you?

A. I don't remember other times at this time.

Q. Are you aware, Ms. Gaikwad, that e-mails from you and from Enri were collected, given to Hugh Fryer and he then gave them to Dicey Taylor, do you remember that?

A. No, I was not privy to anything about that.

Q. And in your preparation last night or whenever it was and today, did these lawyers show you any other e-mails than the ones you've discussed here?

A. Some of them, yes.

Q. And were the responses from Richard Hart among those?

A. I haven't -- no, I haven't seen any of those.

Q. Are you aware, Ms. Gaikwad, that Richard Hart's electronically stored information was deliberately destroyed by the plaintiffs in contemplation of this litigation?

MS. HAGBERG: Objection, your Honor.

THE COURT: Sustained. It doesn't matter whether she's aware or not aware. I'm aware.

Q. I believe you testified to what you thought was a lack of

design systems --

A. Design control, yes.

Q. Design control. Okay. Do we have the e-mail that copies everybody on Trinity?

MS. BRILEY: We did put that on the screen earlier because we don't have a printout of it. So I relied on Mitch for an exhibit designation.

MR. VELIE: Your Honor, I will represent to the witness and to the Court, if you will back me up on this, Ms. Gaikwad was among the many people copied on the e-mail we all saw earlier saying Trinity was coming to audit.

THE COURT: Yes, I remember it in fact.

Q. I'm now going to read to you -- were you aware of a Trinity Biotech audit?

A. No.

Q. Are you aware of what I call perhaps ignorantly a customer audit, which perhaps you might call a supplier audit just generally as a practice?

A. Yes. I know what it is, yes.

Q. And is Trinity Biotech a customer?

A. Yes.

Q. So if they are auditing ADI you'd call it a supplier audit or would you prefer to call it --

A. Customer audit.

Q. Customer audit. Thank you.

MR. VELIE: One moment, your Honor. We are having technical difficulties.

(Pause)

MR. VELIE: I apologize. I will have to find this and we'll read it either into the record or to another witness if we have to.

Q. I do have another audit, however. Are you aware that the company from time to time gets ISO certified?

A. Yes.

Q. Apparently this audit which is Exhibit DX P, as in Peter, is dated 4/14/2009 to 4/16/2009, a three-day audit. And I understand that this is about a month and a half, is that correct, prior to closing?

MS. BRILEY: Six days.

Q. This is immediately before the closing, six days before the closing. I want you to turn with me to page ending 301. Do you see that the auditor checked 7.31, design and development planning, design and development inputs --

MS. HAGBERG: Your Honor --

Q. Design and development outputs, design and development review --

MS. HAGBERG: Pardon me a minute, Mr. Velie. I object to him reading another audit into the record without establishing that she knows anything about it or can say anything about it.

THE COURT: The point is, it's time, my time to sit here while you read it. I can read it. What question do you want to ask her?

Q. The question I'm going to ask her, she testified there were absolutely no such procedures in place and the auditor found them. You simply disagree with the auditor, is that right, Ms. Gaikwad?

A. No. If the procedures, like I said before, the procedures were in place they were only as part of the computer system but we never implemented them which was more important for me.

Q. So you can't tell us what was implemented in manufacturing, is that correct?

A. The design control procedure is implemented for R and D department.

Q. And you say that in your department you didn't implement these procedures?

A. None of us did that.

Q. And you say that despite the fact that the auditor came, audited and found that this was satisfactory?

A. I'm seeing this for the first time. I don't know what you're referring to now, so --

Q. Let's now go back to the exhibit I was going to use which is the Trinity Biotech audit.

MS. BRILEY: That was admitted -- offered into evidence. We haven't formally admitted it, DX S.

THE COURT: We still have that here.

MR. VELIE: And I'm on page 926.

MS. HAGBERG: Could you wait a minute? Unless you have another copy.

MS. BRILEY: I think I can find you one. Just one moment.

Q. Are you looking with me at page 926? Bottom box.

A. 926?

Q. Yes.

A. I don't know --

Q. It's SEK 00108926.

A. I have SEK 00327304.

MS. BRILEY: You're correct, I'm sorry, I have not given you your copy yet. My apologies. A little bit behind.

MR. VELIE: Could you show her the page?

MS. BRILEY: What page did you say?

MR. VELIE: 926.

MS. BRILEY: It will be the third page of the document right here.

Q. The Trinity auditor, you were notified that Trinity would be there. Do you remember Trinity coming to your department?

A. To my department I don't remember.

Q. You don't remember. Is the supplier responsible for the design and development of the products to be purchased? There's an X yes. Complete questions below. Does the supplier

document design input requirements? Yes. See SOP GEN 01 section 4.4.

MS. HAGBERG: Objection, your Honor. We're reading the same document in again.

MR. VELIE: Yes.

THE COURT: But she's saying you don't need to read it into the record any longer, that's been done. You can ask the witness to review it and just say do you disagree with this audit.

Q. Do you disagree with what the auditor found?

A. Like I said earlier, we had the documents, all kind of documents in place but we never implemented them as employees.

Q. It says here, "Does the supplier document adequate design output requirements which would include acceptance criteria requirements, calculations and analysis?" And it says it was reviewed at audit.

MS. HAGBERG: Objection, your Honor, that is not within her job responsibilities as he established.

THE COURT: That's all right. She seems to be taking issue with that. That last part he read you, can you say that's not so?

A. We did not implement this as a routine procedure in the company.

Q. Oh, okay, so your testimony now is that sometimes you did, sometimes you didn't?

A. No. I'm saying that all the documents were there on the computer, yes, to show, but we did not have any actual implementation of these procedures in order to do any kind of design work.

Q. Are you aware that Trinity was actually auditing the product that it's buying from ADI?

A. Which product was it buying?

Q. 8430.

A. I wasn't aware of that.

Q. I'm sorry, 843L.

MS. HAGBERG: I believe the witness gave an answer to the question. She said, "I was not aware of that."

MR. VELIE: Okay, thank you. May I have a second, your Honor?

(Pause)

Q. We can go back to product 101201. When you sent your 2010 e-mail the problem you perceived in 2010 was with respect to a lot or lots in 2010, isn't that correct?

A. The manufacture -- in 2010 when we had a remediation effort which was because -- it was many, many products. The problems we had were, we all were like working round the clock to fix the issues with the products. At that time any product which they made was not passing within the specifications as whatever specifications were put in the SOPs at the time and we were trying to figure out as to what the issue was. With 101201

when it was brought to my attention I immediately send them the information which I had from 2004 asking them to look into the tPA standard.

MR. VELIE: I move to strike the non-responsive portion of the answer.

Q. I'm going to press my question, Ms. Gaikwad. When you did your work, if any, remediating product 101201 it was with respect to lots that were manufactured in and around 2010, isn't that correct?

A. Which was manufactured, it was a recent lot which was manufactured at that time.

Q. Thank you.

A. Whenever it was manufactured.

MS. BRILEY: We didn't have time to get this one printed.

MS. HAGBERG: Your Honor, I'm going to object for the same reasons that they have objected, that it's outside of the relevant time period.

MR. VELIE: She testified to this and in addition to which she testified to a 2004 e-mail and the fact that there were no procedures and no meetings.

THE COURT: The reason, the 2004 e-mail was forwarded in 2010 to address the continuing problem. I don't know what's in this e-mail.

MR. VELIE: Judge, she testified that there were no

procedures and there was no training.

THE COURT: Right, she did.

MR. VELIE: This will address that.

THE COURT: All right. If it's used to impeach her testimony I will allow it.

Q. Were you a recipient of this e-mail from Leigh Ayres?

A. Yes, my name is there.

Q. This is October 7, 2005?

A. Yes.

Q. Okay. Do you recall it?

A. I don't -- I haven't got a chance to read the contents but I can --

MS. HAGBERG: Could you move it down so we could see it?

MS. BRILEY: Can you make it a little bigger?

MR. WHITNEY: Hand it to the witness so she can read it.

MS. BRILEY: She has it on her screen. We don't have a hard copy.

THE COURT: So they would like to be able to read it. All right, it's clearer now.

Q. It invites you to please attend a procedure development meeting planned for Tuesday October 11, 2005 at 3:00 p.m., right? Is that correct?

MS. HAGBERG: Your Honor, could he just make sure that

she's done looking at the e-mail?

THE COURT: Are you still reading it?

A. This is -- yes. What I'm getting is, this is about the package insert for the package.

THE COURT: What? The package insert?

A. Package insert only meeting.

MR. VELIE: Unfortunately, your Honor, we don't have all Leigh Ayres e-mails and all Richard Hart's e-mails. This one we have and it shows she was invited to a meeting for training on a particular SOP.

THE COURT: Where does it say that?

MR. VELIE: In the first paragraph.

MS. BRILEY: A.

THE COURT: The agenda for this meeting is to review a draft -- I don't notice the word "training".

MR. VELIE: "I will bring copies of these procedures to the meeting. The advisory board would like the team to apply the package insert procedure a draft as a priority. The agenda for this meeting is to, A, review the GEM," whatever it is, "draft; B, review and discuss a proposed outline for the summary and explanation of the methods section of the package insert for the combined kit." It goes on from there.

Q. In fact, this was a training meeting, isn't it, for people interested in this procedure?

MS. HAGBERG: Objection to the description of the

procedure development.

THE COURT: Do you know if you went to the meeting?

THE WITNESS: Of course I went to the meeting, but I have a problem with saying that I was trained on something which we never got trained to implement things.

THE COURT: So you didn't get trained.

THE WITNESS: No.

THE COURT: Okay.

Q. And they did have a design control SOP, isn't that correct? It shows on the screen.

A. GEN 41A draft, if I remember correctly, this is again going back, we had lots of revisions of this SOP just because nobody was able to agree on what was written in that.

Q. Was it your testimony when Ms. Hagberg was asking you questions that they didn't even have an SOP?

A. Well, if I tell you an SOP is reviewed and approved and you're trained on it, it is not called that the system is in place as far as control is concerned.

Q. Your problem with this is they were trying to train you on an SOP that was in circulation to the team, is that right?

A. It was still in circulation. It was not in any shape or form that we were able to follow it through.

Q. Okay, I now understand what your complaint is.

MR. VELIE: Again, your Honor, I need a moment.

(Pause)

MR. VELIE: Thank you, Ms. Gaikwad.

MS. HAGBERG: Just a couple of questions on redirect, Ms. Gaikwad.

REDIRECT EXAMINATION

BY MS. HAGBERG:

Q. I believe your testimony was not what Mr. Velie said, there was a form there just no one could follow it. Is that what your testimony was?

MR. VELIE: Objection to leading, even on redirect.

Q. If you could look --

THE COURT: One moment, please. I'm actually sustaining that objection. That's not a good question.

MS. HAGBERG: Okay. Could you put up the document we were just looking at. I don't recall what the document -- thank you.

Q. Would you look at this again? What is GEN 41? Do you know Ms. Gaikwad?

A. It is a design control procedure which Leigh was trying very hard to put in this company.

Q. Was that one of the forms that you were talking about that was in existence but was not really implemented?

MR. VELIE: Objection to leading.

A. Yes, there are many forms associated with GEN 41 as part of the design control procedure. There should be a -- yes. Like I said, this was not even really in a shape where we were able

to move ahead with whatever the contents written in this SOP was, so I'm not sure if the forms were even made at this time.

Q. And when -- did Ms. Ayres have meetings with employees where she tried to talk about training?

A. Yes. There used to be a group of individuals who used to be called, typically a training used to be reading the SOP in front of a group of individuals and if anybody had any questions they were supposed to ask -- I don't know, none of the employees felt that the training was sufficient enough to apply it on their daily job.

Q. And did the employees follow, did the directors follow the forms that Ms. Ayres was trying to implement?

A. No. Like I said, she tried, but it was very difficult to pass through that management anything which was supposed to be, what she expected to do.

Q. Could you please look at PTX 201 in your binder?

MR. VELIE: This is beyond the cross, your Honor.

THE COURT: Isn't this the meeting?

MS. HAGBERG: This is another meeting but it relates to the same GEN 41.

THE COURT: I'll allow it.

Q. And if you look at the back page you see what was attached to the e-mail that was to be discussed at the meeting that Ms. Ayres refers to in her cover e-mail?

A. Yes.

Q. What were the two GENs that she was talking about?
A. I believe it is the part of GEN 21 which is a risk analysis document. Again, risk analysis is also a part of a design, you know, control procedure. You have a GEN 41 and then there are associated forms associated with it.
Q. Is it also GEN 41 if you see the next file?
THE COURT: What do you mean next file?
Q. Look at page SEK 959 of PTX 201.
THE COURT: What's there at 959?
MS. HAGBERG: It just has file GEN 21, file GEN 41.
THE COURT: Okay.
A. Like I say, the forms are part of GEN 4 is design control.
Q. What is a GEN document?
A. I mean, there are multiple GEN documents.
Q. Generally what is a GEN document? What are they supposed to be?
A. They are mostly related to QA, compliance-related documents.
Q. Are those the documents that you said that you were given and no one could understand what they were?
A. Yes.
Q. And do you see Mr. Teicher's cover e-mail, the first page of this document, August 2, 2006 at 10:29 a.m.?
A. Yes. I mean, this is what typically used to happen in the working environment where nobody wanted to listen to Leigh and

they used to come up with this kind of comments where it was never a constructive criticism of how we move ahead with the project or anything to do with compliance.

Q. And so is Mr. Teicher here telling Ms. Ayres to delete certain portions of her document that were supposed to be, that she was trying to use for compliance?

A. Well here, this is a risk analysis part of the product. She was trying to put together a risk analysis. However --

MR. VELIE: Your Honor, this is well beyond cross.

THE COURT: It is. I agree. Objection sustained.

MS. HAGBERG: All right. I have no further questions.

THE COURT: Thank you. Anything further for this witness? Thank you.

THE WITNESS: Thank you.

(Witness excused)

MS. HAGBERG: I was just going to ask, our last fact witness for today is by video. Do you want us to play that now, your Honor? It's about, what is it, 30 --

MR. WHITNEY: It's about 40 minutes.

THE COURT: Who is that?

MS. HAGBERG: That's Jeff Ellis.

THE COURT: And then what else do you have after Mr. Ellis?

MS. HAGBERG: We're going to call Carrie Kuehn.

THE COURT: That's your last witness?

MS. HAGBERG: We have two witnesses; left Ms. Kuehn and Mr. Erb, our experts.

THE COURT: You have two more live witnesses?

MS. HAGBERG: Yes.

THE COURT: You think you'll finish tomorrow?

MS. HAGBERG: Depending on the extent of the cross, but certainly on direct.

MR. VELIE: Your Honor, if it's all right with you, our team has been losing a lot of sleep keeping up with this and we would like to break at the usual time at 4:30.

THE COURT: Oh, yes, no question about that. It's only a few minutes.

MR. KORTMANSKY: Your Honor, we've met and conferred with counsel regarding what excerpts they're going to use for Mr. Ellis and we have actually come to an agreement on most of the excerpts they're going to use. We have three objections which I've notified counsel. Because of your conference on December 18 you said you could clear it up yourself, that's what you said, I could simply let you know what our objections are remaining before Mr. Ellis starts, you have them noticed and Mr. Ellis can be entirely read in with our objections.

THE COURT: That's fine. I'm not sure how you intend to submit it to me in advance.

MR. KORTMANSKY: I have it in writing.

THE COURT: You have the question and answer and the

objections?

MR. KORTMANSKY: These are our objections --

THE COURT: Would you have a transcript to look at so I could figure out whether to sustain or overrule the objections?

MR. WHITNEY: This was dealt with at the pretrial conference. If you recall your law clerk reviewed the Ellis transcript and you ruled that you thought it was sufficient to come in and if there was something that was out of the scope you could typically ignore it -- I don't want to characterize what you said. It's in the transcript. If you want it read in the transcript here today.

MR. KORTMANSKY: Alternatively I can ask them to pause when I need to make my objections and I can make my objections at that time.

THE COURT: Okay.

MR. KORTMANSKY: If that works for you.

THE COURT: Okay. Now, after the deposition reading and the two experts who are going to testify, Ms. Kuehn and Mr. Erb, then how much does the defendant have? What are you thinking of now?

MR. VELIE: Your Honor, we need to see what Ms. Kuehn has to say.

THE COURT: It's not going to be a big surprise. She's limited to her report.

MR. VELIE: True enough.

THE COURT: I'm saying have you thought about how many witnesses you'd be calling. You know what Ms. Kuehn is going to say. You have her report.

MR. VELIE: May we report on that in the morning, your Honor?

THE COURT: It's not terribly helpful. Tomorrow is Thursday. Most of us would like to know whether we're finishing on Friday or on Saturday, but okay. Okay. Please be prepared to report in the morning so we all know what we're doing. Thank you.

MS. BRILEY: And finally I just want to make sure, one easy thing, get the exhibits entered into evidence.

THE COURT: Okay.

MS. BRILEY: So for defendants we introduced and moved to enter DX seven J's, DX six A's, DX six B's, DX six C's, DX five I's, DX five H's, DX four J's, DX seven H's, DX seven I's, DX seven J's and we also used PTX 31 and I just don't know whether it had already been entered into evidence. So I will move that.

THE COURT: So you will what?

MR. VELIE: We'll move it in.

THE COURT: All right.

MS. HAGBERG: Your Honor, may I have until tomorrow morning to review that list, because I don't have my notes if

it's from prior witnesses.

THE COURT: Okay. Okay.

MS. HAGBERG: Thank you, your Honor.

THE COURT: Okay, thank you. See you tomorrow.

COUNSEL: Thank you, your Honor.

(Adjourned)

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